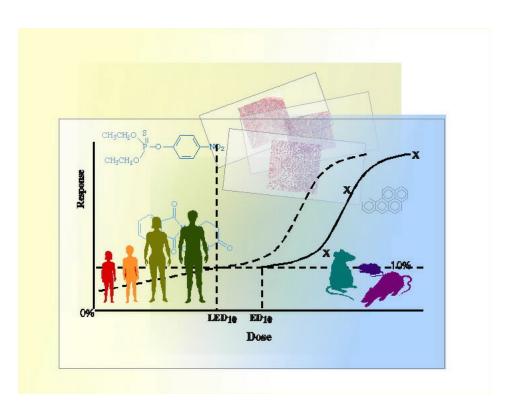
HUMAN HEALTH RISK ASSESSMENT

BENSULIDE



U.S. Environmental Protection Agency Office of Pesticide Programs Health Effects Division (7509C)

> Kit Farwell, Risk Assessor June 16, 1999

HUMAN HEALTH RISK ASSESSMENT

BENSULIDE

Phase 4

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BENSULIDE: HEALTH EFFECTS DIVISION'S REVISED CHAPTER FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT

TABLE OF CONTENTS

EXE	CUTIVE	SUMMAF	RY			1
I.	Scien	ce Asse	ssment			3
	Α.				al Properties Assessment	
		1.			Chemical	
		2.			of Active Ingredient	
		3.			g Use Products	
		4.			ckground	
		5.	_	•		
	В.				nent	
	В.	пина 1.			sment	
		1.			Toxicity	
			a.			
			b.		ronic Toxicity	
				(1)	GLN 82-2/ 21-Day Dermal Toxicity (Rat)	
				(2)	GLN 82-2/ 21-Day Dermal Toxicity (Rat)	
				(3)	GLN 82-1/90-Day Subchronic Toxicity (Rat)	
				(4)	GLN 82-1/13-Week Feeding Study in Dogs	
			C.		ic Toxicity/Carcinogenicity	
				(1)	GLN 83-5/2-Year Combined Chronic Toxicity/Oncogen	
					Study in Rats	
				(2)	GLN 83-2/18-Month Carcinogenicity Study in Mice	
				(3)	GLN 83-1/1-Year Feeding Study in Dogs	
			d.	Develo	ppmental Toxicity	
				(1)	GLN 83-3/Developmental Toxicity Study	
				(2)	GLN 83-3/Developmental Toxicity Study	16
			e.	Repro	ductive Toxicity	17
				(1)	GLN 83-4/2-Generation Study of Reproduction	17
			f.	Mutag	enicity	19
				(1)	GLN 84-2/Mutagenicity (Category I)	
				(2)	GLN 84-2/Mutagenicity (Category I)	
				(3)	GLN 84-2/Mutagenicity (Category II)	
			g.		al Metabolism	
			9-	(1)	GLN 85-1/Metabolism and Pharmacokinetics	
			h.		toxicity	
				(1)	GLN 81-7/Delayed Neurotoxicity in the Hen	
				(2)	GLN 81-8ss/Acute Neurotoxicity in the Rat	
		2.	Dose/F		se Assessment	
		۷.	a.		al Sensitivity to Infants and Children	
			b.		ogenic Classification	
			D. С.		ppmental Classification	
			_		•	
			d.		Il Absorption	
		•	e. Dietem		ological Endpoints	
		3.	-	•	ure and Risk Assessment/Characterization	
			a.	-	y Exposure (Food Sources)	
				(1)	GLN 860.1200: Directions for Use	
				(2)	GLN 860.1300: Nature of the Residue - Plants	31

			(3)	GLN 860.1300: Nature of the Residue - Livestock 32
			(4)	GLN 860.1340: Residue Analytical Methods 32
			(5)	GLN 860.1360: Multiresidue Methods
			(6)	GLN 860.1380: Storage Stability Data
			(7)	GLN 860.1500: Crop Field Trials
			(8)	GLN 860.1520: Processed Food/Feed
			(9)	GLN 860.1480: Meat, Milk, Poultry, Eggs
			(10)	GLN 860.1400: Water, Fish, and Irrigated Crops 35
			(11)	GLN 860.1460: Food Handling
			` '	GLNs 860.1850 and 860.1900: Confined/Field Accumulation
			(12)	in Rotational Crops
			(13)	Tolerance Reassessment Summary
			` '	Codex Harmonization
		L	(14)	
		b.	•	Risk Assessment and Characterization
			(1)	Dietary Exposure Assumptions
			(2)	Acute Dietary Exposure and Risk
			(3)	Chronic Dietary Exposure and Risk
			(4)	Carcinogenic Risk
		C.		g Water
			(1)	$\textbf{Calculation of Drinking Water Levels of Comparison} \dots \ 43$
			(2)	Comparison of Chronic DWLOCs to Estimated Drinking
				Water Concentrations
			(3)	Comparison of Acute DWLOCs to Estimated Drinking Water
				Concentrations
	4.			and Residential Exposure Risk Assessment and
		Charac	terizatio	on
		a.	Occupa	ational and Residential Exposure45
			(1)	Summary of Available Products and Use Patterns 45
			(2)	Summary of Toxicology Information 50
			(3)	Handler Exposure Scenarios 51
			(4)	Handler Exposure Assessment
			(5)	Post-Application Exposure Scenarios
			(6)	Post-Application Exposure Assessment
		b.		ational and Residential Risk Assessment/Characterization
				89
			(1)	Methods For Calculating Risks From Calculated Exposures
			(-)	
			(2)	General Risk Characterization Considerations
			(3)	Occupational and Residential Handler Risk Summary 96
			(4)	Post-Application Occupational Risk 105
			(5)	Post-Application Residential Risks
			(6)	Incident Reports
	5.	Aggrega		osure
	J.	a.		Aggregate Exposure Assessment
		a. b.		
				C Aggregate Exposure Assessment
		C.		erm Aggregate Exposure Assessment
			(1)	Drinking Water Calculations for Short-term Aggregate
			(0)	Exposure
			(2)	Intermediate-term Aggregate Exposure Assessment 120
VDDENIDIA V				
AFFENDIA A				
APPENDIX B				

APPENDIX C .				 	 	 	 		 	 		 	 		 	 	 	 	. '	150
EXECUTIVE	CHMI	МΔΙ	PV																	

This document is the **third** version of Health Effects Division's (HED's) Chapter for the Reregistration Eligibility Decision Document (RED) for Bensulide and was written after the registrant's and public comments were addressed. The registrant's comments did not result in significant changes to the original risk assessment (see 12/22/98 memos from Kit Farwell and Jeff Dawson).

This document has been revised because new studies have recently become available. The occupational and residential exposure assessment was re-calculated for this document because new toxicity endpoints for dermal exposure based on the newly available toxicity data were selected and a new turf study was available for calculation of dermal exposure. The previous dermal exposure endpoints were from oral toxicity studies and used calculated dermal absorption values. A new 21-day dermal exposure toxicity study was recently completed. The endpoint for short-term and intermediate-term dermal exposure is now the no-observed-adverse-effect level (NOAEL) from this 21-day dermal toxicity study in rats (see the dose response section of this memo for more details). A dermal absorption factor was not needed since the toxicity occurred as a result of dermal exposure. Dietary exposure and risks were recalculated with the Dietary Exposure Evaluation Model (DEEMTM), which used more recent consumption data than did the previous dietary analysis with the Dietary Risk Evaluation System (DRES).

Dietary Risk

Acute and chronic dietary exposures are less than 1% of acute and chronic RfDs (less than 100% of the RfD is considered protective). The calculated dietary exposures are significantly below HED's level of concern, and are relatively similar to the DRES estimates (when results at similar tiers of analysis are compared).

Drinking Water

Monitoring data for bensulide in drinking water were limited so drinking water levels of comparisons were calculated for acute and chronic risk. Acute drinking water exposure based on modeling estimates is not of concern, but estimated chronic surface water exposure is of concern. When turf use is eliminated, surface water concentrations are comparable to drinking water levels of comparison and are not of concern for adults, however concerns remain for children and infants. Chronic ground water exposure is not of concern.

Occupational Risk

Generally, the Agency has few concerns over the use of bensulide in agriculture. The Agency does have some concerns over the uses of certain application methods for occupational uses on golf courses and in residential settings. The Agency is concerned about the use of a bellygrinder by homeowners to treat residential turf.

HED does not consider post application exposure in agricultural settings problematic due to the cultivation practices anticipated with the pre-plant/pre-emergent use of bensulide. This evaluation is based on an assessment of bensulide labeling and available use information. However, HED requests that additional information be submitted pertaining to cultural practices of the labeled crops in order to refine this assessment.

The results of the post-application assessment for adults are more refined (because of the recently submitted data) and are significantly different from the previous assessment. Following the watering in of bensulide (keeping in mind the monitoring study used about 0.5 inches of water for irrigation) MOEs are greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate. If the watering in was not as extensive as completed in the study, MOEs are still greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate.

The results of the post-application risk assessment for children are also more refined. Following the watering in of bensulide, the MOEs for dermal exposures were greater than 100 on the day of application even at the highest application rate for children in high exposure activities (e.g., hard play) over a long duration. If the watering in was not as extensive (0.5 inches) as completed in the study, MOEs for dermal exposures are still greater than 100 on the day of application for children in high exposure activities (e.g., hard play) over a long duration at the lowest application rate, but not at the maximum application rate.

The completion of separate short- and intermediate-term risk assessments for residential bensulide post-application exposures is no longer appropriate because the same endpoint is used for both durations of exposure, the exposure values are the same, and the TTR study data also indicate that bensulide also dissipates in a manner that is not conducive to the use of an intermediate-term post-application risk assessment.

Aggregate Risk

Aggregate risk (non-occupational and residential risks) to adults and children was calculated. Acute and chronic aggregate exposure consisted only of food and drinking water exposure and are described in the drinking water section above. Short-term aggregate risk consisted of food and residential (dermal, inhalation, and non-

dietary oral) exposures. Short-term aggregate risk was not of concern, nor were estimated drinking water concentrations. An intermediate-term aggregate assessment was not calculated because it would have resulted in less exposure and risk than in the short-term aggregate assessment.

I. Science Assessment

A. Physical and Chemical Properties Assessment

1. Description of Chemical

Bensulide [S-(O,O-diisopropyl phosphorodithioate) ester of N-(2-mercaptoethyl) benzenesul-fonamide] is an herbicide registered for food/feed uses on Brassica leafy vegetables, carrots, cucurbits, fruiting vegetables, leafy vegetables, garlic, dry bulb onions, and shallots.

$$\begin{array}{c|c} & & & S \\ O & H & & || \\ S & N & & S \\ S & / & OCH(CH_3)_2 \\ O & OCH(CH_3)_2 \end{array}$$

Empirical Formula: $C_{14}H_{24}NO_4PS_3$

Molecular Weight: 397.5 CAS Registry No.: 741-58-2 Shaughnessy No.: 009801

2. Identification of Active Ingredient

Pure bensulide is a colorless solid with a melting point of 34.4°C. Technical bensulide is a viscous amber liquid at temperatures above 34°C and a solid below this temperature. Bensulide is soluble in water at 25 ppm at 20°C and is miscible with acetone, ethanol, 4-methylpentan-2-one, and xylene.

3. Manufacturing Use Products

A search of the Reference Files System (REFS) conducted 4/15/97 identified two bensulide manufacturing-use products (MPs) registered under Shaughnessy No. 009801: the Gowan Company 92% T and 46% FI (EPA Reg. Nos. 10163-201 and 10163-202). Because bensulide is a List B chemical, only the 92% T/TGAI is subject to a reregistration eligibility decision.

4. Regulatory Background

The current status of the product chemistry data requirements for the bensulide technical product is presented in Table 1. Refer to this table for a listing of the outstanding product chemistry data requirements.

Case Name: Bensulide

Registrant: Gowan Company

Product(s): 92% T (EPA Reg. No. 10163-201)

Table 1. Product Chemistry Data Summary

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²				
830.1550	Product Identity and Disclosure of Ingredients	Y 3	00088284 ⁴ , 00163310 ⁴ , 42685001 ⁵ , CSF 2/26/93 ⁶				
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Υ	00163310				
830.1670	Discussion of Formation of Impurities	Υ	00163310				
830.1700	Preliminary Analysis	Y	00163299, 40033501				
830.1750	Certification of Ingredient Limits	Y	00163299, ÇSF 2/26/93				
830.1800	Analytical Methods to Verify the Certified Limits	N ⁷	00163299, 40033501				
830.6302	Color	Υ	41532001				
830.6303	Physical State	Υ	41532001				
830.6304	Odor	Υ	00157314				
830.6313	Stability	N ⁸	41532001				
830.7000	рН	Υ	41532001				
830.7050	UV/Visible Absorption	N ⁹					
830.7200	Melting Point/Melting Range	Υ	41532001				
830.7220	Boiling Point/Boiling Range	N/A ¹⁰					
830.7300	Density/Relative Density/Bulk Density	Υ	41532001 ⁴ , 42685001 ⁵				
830.7370	Dissociation Constant in Water	N/A ¹¹	41532001				
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	Y	00157314				
830.7840 830.7860	Solubility	Y	41532001				
830.7950	Vapor Pressure	Υ	41532001				

¹ Y = Yes; N = No; N/A = Not Applicable.

² References reviewed under CBRS No. TBA, DP Barcode TBA, currently under review, unless otherwise noted.

³ We note that the label claim of 92% is not in agreement with the nominal concentration of the active ingredient listed on the CSF.

⁴ CBRS No. 9532, D173998, 9/15/92, F. Fort.

⁵ CBRS No. 11574, D189279, 4/22/93, K. Dockter.

⁶ The CSF was obtained from the product jacket.

⁷ Supporting validation data are required for the analytical methods used for the quantitation of three impurities present at ≥0.1%.

⁸ Data reflecting the stability of the TGAI on exposure to metals and metal ions are required.

⁹ The OPPTS Series 830, Product Properties Test Guidelines provide guidance on determining UV/visible absorption for the PAI, proposed (Draft 40 CFR Part 158) to be required.

¹⁰ Data are not required because the TGAI is a solid at room temperature.

¹¹ Data are not required because bensulide is not an acid or a base.

5. Conclusions

Most pertinent data requirements are satisfied for the bensulide 92% T/TGAI; however, additional data are required concerning OPPTS 830.1800 and 830.6313. In addition, data are required concerning UV/visible absorption for the PAI (OPPTS 830.7050). Provided that the registrant submits the data required in Table 1 for the 92% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the bensulide TGAI have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of bensulide with respect to product chemistry data requirements. A tomato processing study necessary to fulfill the reregistration requirements for magnitude of the residue in the processed commodities of imported tomatoes is presently under review.

B. Human Risk Assessment

1. Hazard Assessment

Toxicology data are used by HED to assess the hazards to humans and domestic animals. The data are derived from a variety of acute, subchronic, and chronic toxicity tests; developmental/ reproductive tests; and tests to assess mutagenicity and pesticide metabolism. Reregistration eligibility decisions require that HED have sufficient information to select the appropriate end-points for performing a human health risk assessment. This requires a toxicological database that is not only complete, but of acceptable quality.

The toxicity database for bensulide is complete and will support a reregistration eligibility determination for the currently registered uses.

a. Acute Toxicity (81-Series)

Table 2 summarizes the acute toxicity of bensulide, technical grade, by different routes of exposure. The purity of the bensulide used in these studies ranged from 92.4 to 93.8 percent.

Table 2. Acute Toxicity Values of Technical Bensulide

Table 2. Acute Toxicity Va	alues of Technical Bensulide	Tovicity
Test	Result	Toxicity Category
Oral LD₅₀ in rat (MRID No.: 00097921 and 92005011) Date 2/21/78	LD ₅₀ = Males: 360 (315-411) mg/kg Females: 270 (238-306) mg/kg Acceptable/Guideline	II
Dermal LD₅₀ in rat (MRID No.: 41597501) Date 5/18/89	LD ₅₀ = > 2000 mg/kg (limit test) Males and females Acceptable/Guideline	Ш
Dermal LD ₅₀ ; in rabbit (MRID No.: 00097921) Date 2/21/78	LD ₅₀ > 5000 mg/kg (limit test) Males and females Acceptable/Guideline	IV
Inhalation LC ₅₀ in rat (MRID No.: 41646201) Date 5/17/89	LC ₅₀ > 1.75 ± 0.120 mg/L Males and females Acceptable/Guideline	Ш
Eye irritation in rabbit (MRID No.: 41597502) Date 5/17/89	Mild irritant, causing mild conjunctival irritation [slight redness (6/6 animals); slight to severe discharge (5/6); no corneal or iridial effects] clearing within three days Acceptable/Guideline	Ш
Dermal irritation in rabbit (MRID Nos.: 00097921 and 92005012) Date 2/21/78	Mild irritant; primary dermal irritation index = 0.5	IV
Dermal sensitization in guinea pig (MRID No.: 00160075) Date 5/20/86	Not a sensitizer; did not cause dermal irritation. Acceptable/Guideline	N/Aª
Acute delayed neurotoxicity in hen (MRID Nos.: 43306301 and 43334302) Date 7/12/94	Did not induce delayed neurotoxicity in the hen. Acceptable/Guideline	N/A
Acute oral neurotoxicity in rat (MRID No.: 43195901) Date 5/23/94	NOAEL for neurotoxicity = 100 mg/kg, based on flaccid abdominal and/or body tone and pinpoint pupils in females at 150 mg/kg (LOAEL). The plasma cholinesterase (ChE) inhibition LOAEL is 50 mg/kg, based on 80% inhibition (no p) of plasma cholinesterase activity in females on Day 0. The plasma ChE NOAEL is 15 mg/kg. The RBC ChE inhibition LOAEL is 150 mg/kg, based on 37% inhibition (p ≤ 0.01) of RBC ChE activity in females on Day 0. The RBC ChE NOAEL is 50 mg/kg. The brain ChE inhibition LOAEL is 150 mg/kg, based on 18% inhibition (no p) of brain ChE activity in females on Day 0 and 27% inhibition (p ≤ 0.01) on Day 15. The brain ChE NOAEL is 50 mg/kg.	N/A
	Acceptable/Guideline	

^aNot applicable

b. Subchronic Toxicity

(1) GLN 82-2/21-Day Dermal Toxicity (Rat)

In a 21-day dermal toxicity study (MRID 42162002), male and female specific pathogen-free Wistar-derived albino rats (Alpk:APfSD strain; 5/sex/dose; 6-8 weeks old) were dermally treated over a 5 cm x 10 cm area of clipped dorso-lumbar skin with bensulide technical (92.7% a.i.) at dose levels of 0 (sham control), 10, 100, and 1000 mg/kg/day (limit test dose). Dosing occurred 21 times over a period of 30 days (five days/week). Following each dosing, the application site was covered with an occlusive dressing (gauze patch, a patch of plastic film secured by adhesive bandages, and two pieces of 2.5 cm-wide PVC tape wrapped around the animals) for approximately 6 hours. After each 6-hour exposure period, the dressings were removed and the application sites washed with warm water. On dosing days, animals were fitted with Elizabethan collars to prevent test substance ingestion. Rats were observed for clinical signs and dermal irritation prior to dosing, after each removal of dressings, and at least once daily during non-dosing days. They were weighed daily, and food consumption was recorded twice weekly. At study termination, cardiac blood samples were collected shortly after animal sacrifice for hematological and clinical chemistry determinations. Gross necropsies were conducted, the standard set of organs were fixed for potential histopathology, and the following organs were also weighed: adrenals, brain, kidneys, liver, and testes (males). Only the kidneys of all animals, and the treated and untreated skins and livers of the control (0 mg/kg/day) and high-dose (1000 mg/kg/day) were examined histologically.

There were no deaths, compound-related clinical signs, or significant changes in body weight or food consumption in any group. A small incidence of dermal trauma was apparently caused by the bandages. No abnormal hematology was seen, and the only clinical chemistry anomaly was a 43% decrease in plasma triglycerides in the high-dose (1000 mg/kg/day) males compared to controls; females were not affected. In the absence of other findings, this decrease is of unknown

biological significance. There were no dose-related gross lesions or organ weight changes. Some scabbing of treated and untreated skin, due to bandage trauma, was observed in all groups. This observation correlates with several histopathologic findings of slight to minimal acanthosis, parakeratosis, and inflammatory infiltration in treated and untreated skin. A number of minimal to slight renal lesions were observed, but they are not clinically significant and may have represented artifacts. Therefore, the NOAEL is > 1000 mg/kg/day (limit dose), based on the lack of any observed toxicity, and the LOAEL was not determined.

Although cholinesterase activity was not determined, this study was classified as Acceptable/Guideline and satisfies the Guideline requirement for a 21-day dermal toxicity study (82-2) in the rat.

(2) GLN 82-2/21-Day Dermal Toxicity (Rat)

In a special 21-day dermal toxicity study (MRID 44801101 & 44809401), groups of Charles River CD rats (10/sex/dose) were dermally applied Bensulide technical (92.1%) at dose levels of 0, 30, 50, and 500 mg/kg for 6 hrs/day for 21 days. The test chemical did not produce treatment-related clinical signs, mortality, or changes in body weight and food consumption. Clinical chemistry and hematology parameters were not measured. Urinalysis, and organ weights were not determined. However, these parameters were not significantly affected in a previous 21-day dermal toxicity study in rats which were dermally treated up to 1000 mg/kg (MRID 42162002; Tox. Doc. No. 009325).

Bensulide at 500 mg/kg produced statistically significant decreases (p<0.01) in plasma cholinesterase (PChE) activity in both males and females on days 7, 14, and 22; the decrease (-31% in males & -55% in females) was particularly marked at the end of the study (day 22). In addition, the inhibition of PChE appeared to increase with the increased time of treatment. Plasma cholinesterase inhibition was also seen in 50 mg/kg females, but it was not statistically significant. Bensulide at 500 mg/kg also significantly (p<0.05)inhibited brain stem ChE activity in both males and females, but it had no effect on the ChE activity

in cerebellum and cerebral cortex. In this study, RBC ChE activity was not affected by bensulide.

Therefore, under the conditions of this dermal toxicity study, the LOAEL for ChE inhibition was 500 mg/kg based on significant inhibition of both brain and PChE activity, and the NOAEL was 50 mg/kg.

The study was classified as Acceptable/non-guideline because this was a special study conducted to obtain information on the potential of bensulide to inhibit ChE activity in plasma, RBC, and brain.

(3) GLN 82-1/90-Day Subchronic Toxicity (Rat)

In a subchronic toxicity study (MRID 43919601), male and female Sprague-Dawley rats (10/sex/dose) were given bensulide (92.4% a.i.) in the diet for 13 weeks at doses of 0, 5, 15, 45, or 100 mg/kg/day.

Significantly decreased body weight gains (p<0.01, 19%) were observed for male rats at 100 mg/kg/day. Although not significant, body weight gains for female rats were 12, 11, and 14% lower than controls at 15, 45, and 100 mg/kg/day, respectively. Food consumption appeared not affected by treatment. Overall food efficiency was decreased in males at 100 mg/kg/day.

Significantly increased alanine amino-transferase levels were observed at 45 mg/kg/day (87% increase in males; 48%, females) and 100 mg/kg/day (145%, males and 90%, females). Dose-related inhibition of ChE activity occurred in both sexes. Relative to controls, plasma ChE decreases were 28, 54, and 62% (males) at 15, 45, and 100 mg/kg/day, respectively, and 19, 47, 84, and 90% (females) at 5, 15, 45, and 100 mg/kg/day, respectively. Red blood cell ChE decreases were 47 and 59% (males) and 38 and 66% (females) at 45 and 100 mg/kg, respectively. Brain ChE decreases were 18 and 43% (males) at 15 and 100 mg/kg/day, respectively, and 28 and 58% (females) at 45 and 100 mg/kg, respectively. Increased relative liver weights were observed in males (17%, p<0.01) and females (19%, p<0.001) at 100 mg/kg/day. The hepatic toxicity was

corroborated by mild histological changes in the liver in males (fatty microvesicles at 100 mg/kg/day; vacuolation at 45 and 100 mg/kg/day).

Under the conditions of this study, the NOAEL is 5 mg/kg/day; the LOAEL is 15 mg/kg/day, based on decreased plasma ChE activity in both sexes, decreased brain ChE activity in males, and an equivocal reduction in body weight gain in females.

This subchronic dietary toxicity study in rats is classified as Acceptable/Guideline and satisfies the guideline requirements (§82-1a) for a subchronic toxicity study in the rat.

(4) GLN 82-1/13-Week Feeding Study in Dogs

In a 13-week subchronic toxicity study (MRID 44052703), bensulide (92.4% a.i., Lot #CBI 0801) was administered via the diet to four dogs/sex/group at dose levels of 0, 1, 3, 10, or 30 mg/kg/day for 13 weeks.

Activated partial thromboplastin times were prolonged in both sexes in the 30 mg/kg/day treatment group at 6 and 13 weeks and in females in the 10 mg/kg/day group at 13 weeks. At 1 mg/kg/day, plasma cholinesterase activities were 38.2 and 22.4% lower in male and female dogs, respectively, at 13 weeks compared to the controls. In the 3, 10, and 30 mg/kg/day treatment groups at 13 weeks, plasma cholinesterase activities were reduced by 61-79% in males and 30-78% in females. Red cell cholinesterase activities in the 30 mg/kg/day group were 12.4% lower for males and 22.4% lower in females at 13 weeks, but these differences were not statistically significant. Pons cholinesterase activities were unchanged by treatment, but cerebellum cholinesterase activities were decreased 35.8% (not statistically significant) in the 30 mg/kg/day group females after 13 weeks of test article administration.

Males in the 1, 10 and 30 mg/kg/day treatment groups had increased absolute (13-19%) and relative (17-22%) liver weights and females in the 30 mg/kg/day treatment group also had increased absolute (20%) and relative (19%) liver weights. Lipid deposits were found in the hepatocytes of 1/4 males in the 3 mg/kg/day treatment group, 1/4 males and 1/4 females in the 10 mg/kg/day group, and 4/4 males and 4/4 females in the 30 mg/kg/day treatment group. No other treatment-related effects were

observed. Mean body weights, body weight gains, and food consumption values were similar in all groups. No neoplastic tissue was observed. The LOAEL for this study is 1 mg/kg/day, based on the reduction in plasma cholinesterase activities in both sexes and increased absolute and relative liver weights in males at this dose level. A NOAEL was not established.

This 13-week subchronic toxicity study is classified Acceptable/Guideline and does meet the guideline requirement for a subchronic oral toxicity study in dogs (§82-1b).

c. Chronic Toxicity/Carcinogenicity (83-series guidelines)

(1) GLN 83-5/2-Year Combined Chronic Toxicity/Oncogenicity Study in Rats

In a combined chronic/oncogenicity study (MRIDS 43919602 and 44161101), bensulide (92.4 ±0.5% a.i., Lot # CBI 0801) was administered in the diet for 104 weeks to 80 Sprague-Dawley rats/sex/group at levels to achieve constant weekly doses of 0, 1, 15, or 60 mg/kg/day. At approximately the 26, 52, and 78 week intervals, 10 rats/sex/group were terminated, and all remaining animals were sacrificed at 104 weeks of the study.

Survival rates, ophthalmoscopic findings, clinical observations, hematological parameters, urinalysis findings, and gross findings were unaffected by treatment with bensulide. Chronic toxicity in rats receiving 60 mg/kg/day was characterized in both sexes by reduced ($p \le 0.05$, <0.01 or <0.001) cholinesterase levels (plasma, $\downarrow 59$ -93%; erythrocyte, $\downarrow 44$ -80%; and brain, $\downarrow 20$ -39%) and, in the males, by increased absolute liver weights ($\uparrow 4$ -22%) and mild histopathological changes of the liver (hepatocyte vacuolation and eosinophilic foci). In the 15 mg/kg/day animals, reduced (p<0.05, <0.01, or 0.001) plasma ($\downarrow 36$ -73%) and erythrocyte ($\downarrow 20$ -40%) cholinesterase activities were also observed.

The chronic LOAEL is 15 mg/kg/day based on inhibition of plasma and erythrocyte cholinesterase activity

in the mid- and high-dose group animals, inhibition of brain cholinesterase activity in the high-dose animals, and increased liver weights and mild histopathological changes in the high-dose males. The chronic NOAEL is 1 mg/kg/day.

Under the conditions of this study, there was no evidence of carcinogenic potential.

Dosing was considered adequate by decreased cholinesterase activity (plasma, red blood cell, and brain) in high-dose animals and by increased absolute liver weights and liver histopathological changes in the high-dose males.

This study is classified as Acceptable/Guideline and satisfies the guideline requirements for a chronic toxicity study (§83-1) and a carcinogenicity study (§83-2) in the rat.

(2) GLN 83-2/18-Month Carcinogenicity Study in Mice

In a mouse oncogenicity study (MRID 44161105), bensulide (92.4 ±0.5% a.i., Lot # CBI 0801) was administered for 78 weeks in the diet to 50 CD-1 mice/sex/dose at levels to achieve constant weekly doses of 0, 1, 50, or 200 mg/kg/day. An additional 10 mice/sex/dose were used to provide samples for plasma and red blood cell cholinesterase assessments at 13 weeks, and further cholinesterase assessments, including brain cholinesterase at 52 weeks; these animals were terminated and discarded at 52 weeks. All remaining animals were sacrificed at 78 weeks of the study.

Survival rates, clinical observations, and hematological parameters were unaffected by treatment with bensulide. Chronic toxicity was characterized by reduced (p<0.01 or <0.001) cholinesterase levels (plasma, \downarrow 92-96%; erythrocyte, \downarrow 40-51%) in the high-dose males and females and reduced brain cholinesterase in the high-dose females (\downarrow 14%). Additionally in the high-dose males, decreased overall body weight gains (\downarrow 32%; p<0.001), increased absolute and relative liver weights (\uparrow 38-43%; p<0.001), and histopathological changes of the liver (pale foci, cell atypia, and cell foci) were observed. In the 50 mg/kg/day animals, reduced (p<0.01, or 0.001) plasma (\downarrow 88-92%) and RBC

(↓31-37%) cholinesterase activities were observed and brain cholinesterase activity was reduced (↓12%; p<0.05) in the females. Additionally, overall body weight gain in the mid-dose males was reduced by 16% (p<0.05) compared to controls.

The chronic LOAEL is 50 mg/kg/day based on inhibition of plasma and erythrocyte cholinesterase activity in the 50 and 200 mg/kg/day group animals, inhibition of brain cholinesterase activity in the mid- and high-dose females, decreased body weight gain in the mid- and high-dose males, and increased liver weights, and histopathological changes in the high-dose males. The chronic NOAEL is 1 mg/kg/day.

Under the conditions of this study, there was no evidence of carcinogenic potential.

Dosing was considered adequate based on decreased plasma, RBC, and brain cholinesterase activities, decreased body weight gains, and by increased liver weights and histopathological changes of the liver.

This study is classified as Acceptable/Guideline and satisfies the guideline requirements for a carcinogenicity study (§83-2b) in mice.

(3) GLN 83-1/1-Year Feeding Study in Dogs

In a chronic toxicity study (MRID 44066401), bensulide (92.4% a.i.) was administered to four dogs/sex/dose by feeding at dose levels of 0, 0.5, 4, or 30 mg/kg/day for 52 weeks. Analytical determinations demonstrated actual bensulide concentrations to be within ± 10% of theoretical values throughout the study. Additional analytical data (MRID 44052704) verified the adequacy of the homogeneity and stability of bensulide in the test diets.

In the 30 mg/kg/day treatment group, there was a 66-73% reduction in plasma cholinesterase activities, a 18.7-35.5% reduction in brain (pons) cholinesterase activities, and a 32-45% reduction in red cell cholinesterase activities. In addition, in the high-dose females, mean body weight

gains were 52% lower than the controls and histopathological changes were observed in the liver. Focal accumulations of pigmented Kupffer cells were observed in 2/4 females, and mild cytoplasmic vacuolation was noted in 3/4 females in the 30 mg/kg/day group. Absolute weights of the adrenal glands of males in the 30 mg/kg/day treatment group were 29% higher than the controls. In the 4 mg/kg/day treatment group, there was a 57-58% reduction in plasma cholinesterase activity, a 24% reduction in brain (pons) cholinesterase activities (males only), and a 34% reduction in body weight gain (females only). In the 0.5 mg/kg/day treatment group, only sporadic reductions in plasma cholinesterase activity were observed in males and females compared to the controls. No animals died during the course of the study, and no treatment-related changes were observed in their appearance or behavior. Food consumption appeared to be unaffected by treatment. No ocular, hematological, or urine abnormalities were detected during the study. No neoplastic tissue was observed in dogs in the treatment and control groups. The LOAEL for this study is 4 mg/kg/day, based on the reduced body weight gains in females, reduced (24%) brain (pons) cholinesterase activity in males, and a 57-58% reduction in plasma cholinesterase activities in both sexes. The NOAEL is 0.5 mg/kg/day.

This chronic toxicity (feeding) study in dogs is classified Acceptable/Guideline and satisfies the guideline requirement for a chronic toxicity study in nonrodents (§83-1b).

d. Developmental Toxicity

(1) GLN 83-3/Developmental Toxicity Study (Rat)

In a developmental toxicity study (MRID 00146585), bensulide technical (92.8 % a.i.) was administered to 25 or 26 female Sprague-Dawley rats/dose in corn oil by gavage at analytically determined dose levels of 0, 5.5, 23.0 or 95.0 mg/kg/day from days 6 through 20 of gestation.

Bensulide technical exerted no effects on maternal gross pathology, fertility, or cesarian parameters. The

maternal systemic LOAEL is 95.0 mg/kg/day (HDT), based on tremors, decreased body weight (range: 93-94% of control value) on days 12, 16, and 21 of gestation, decreased body weight gain during days 9-12 (25% control value) and 6-21 (76% of control value) of gestation, decreased (79% of control value) feed intake during days 13-16 of gestation, and decreased whole and corrected (reproductive tract subtracted) body weights (93% and 91% of control values, respectively) and increased liver/body weight ratio (112% of control value) at study termination. The maternal systemic NOAEL is 23.0 mg/kg/day (MDT).

The Maternal NOAEL for cholinesterase inhibition is 5.5 mg/kg/day (LDT), based on a 48% decrease in plasma ChE activity at 23.0 mg/kg/day (LOAEL; MDT) in the absence of any other effects.

The Developmental NOAEL ≥ 95.0 mg/kg/day (HDT), based on the lack of any developmental effects. The developmental LOAEL > 95.0 mg/kg/day.

This developmental toxicity study in the rat is classified Acceptable/Guideline and does satisfy the guideline requirement for a developmental toxicity study (§83-3a) in the rat.

(2) GLN 83-3/Developmental Toxicity Study (Rabbit)

In a developmental toxicity study (MRID 00152845), inseminated New Zealand White rabbits, randomly assigned to one control and three treatment groups of 18 animals each, were administered Betasan® (bensulide technical; 92.8% a.i.) by oral gavage at doses of 0, 5, 20, or 80 mg/kg/day on gestation days (GD) 7-19, inclusive. Cesarean section examinations were performed on all surviving does on GD 29, followed by teratological examination of all fetuses.

No treatment-related effects were observed in the 5 or 20 mg/kg/day groups as compared with controls. Three high-dose animals aborted, one each on GD 18, 27, and 28, and were sacrificed and necropsied. All other animals survived until scheduled sacrifice. Decreased defecation

was observed in 3, 2, 1, and 11 animals and decreased urination was observed in 3, 2, 0, and 11 animals in the control, 5, 20, and 80 mg/kg/day groups, respectively. No other dose- or treatment-related clinical signs of toxicity were observed during the study. Maternal body weight gains were significantly (p \leq 0.05 or 0.01) less in the highdose group as compared to the controls throughout the dosing interval with an overall weight loss recorded during the treatment interval. Absolute body weights of the highdose animals were less than the controls beginning on GD 13 but statistical significance (p \leq 0.01) was reached only on GD 19. After cessation of treatment, does in the high-dose group showed recovery with body weight gains significantly (p \leq 0.01) greater than the controls. During the dosing interval, food consumption by the high-dose animals was significantly ($p \le 0.01$) less than the control beginning on GD 10. Overall food consumption was significantly less in the high-dose group for the entire dosing interval (62%; p < 0.01) and the entire gestation period (83%; $p \le 0.05$) as compared to controls.

Therefore, the maternal toxicity NOAEL is 20 mg/kg/day and the maternal toxicity LOAEL is 80 mg/kg/day based on reduced body weights and weight loss during the treatment interval.

There were no differences between treated and control groups for live fetuses/litter, fetal body weights, or fetal sex ratios. No treatment-related malformations/variations were observed for any external, visceral, or skeletal parameter examined of kits in the treated litters as compared to the control litters. There was no difference in the total number of litters containing fetuses with major malformations as compared to controls: 3/15, 1/15, 0/10, and 2/10 affected in the control, 5, 20, and 80 mg/kg/day groups, respectively.

Therefore, the developmental toxicity NOAEL is ≥ 80 mg/kg/day and the developmental toxicity LOAEL was not identified.

This developmental toxicity study in rabbits is classified as Acceptable/Guideline and satisfies the

guideline requirement (§83-3b) for a developmental toxicity study in rabbits.

e. Reproductive Toxicity

(1) GLN 83-4/2-Generation Study of Reproduction (Rat)

In a two-generation reproduction study (MRID 43948701), Bensulide (92.4% a.i.; Lot No. CDI 0801) was administered to male and female Sprague-Dawley CD rats in the diet at concentrations of 0, 25, 150, or 900 ppm for two generations. Premating doses for the F_0 males were 2.0, 12.3, and 68.2 mg/kg, respectively, and for the F₀ females were 2.3, 13.2, and 80.8 mg/kg, respectively. Premating doses for the F₁ males were 2.3, 14.0, and 86.5 mg/kg, respectively, and for the F₁ females were 2.6, 15.4, and 93.2 mg/kg, respectively. The F₀ generation contained 28 animals/sex/dose and the F₁ generation contained 24 animals/sex/dose. Animals were given test or control diet for at least 10 weeks then mated within the same dose group. F₁ animals were weaned on the same diet as their parents. At least 21 litters were produced in each generation. All animals were exposed to test material either in the diet or during lactation until sacrifice.

Although several deaths occurred among treated and control groups of both generations, these were considered incidental to treatment. No overt treatment-related clinical signs of toxicity were observed in the adult animals of either sex or generation. There were no statistically significant differences between treated and control groups of either sex or generation for absolute body weights, body weight gains, food consumption, or gross or histopathological findings.

Therefore, the NOAEL for systemic effects ≥ 900 ppm (82.8 mg/kg/day; HDT) and the LOAEL was not determined.

Terminal cholinesterase activity was measured in plasma, red blood cell, and brains of the adult animals of both generations. Baseline or pretreatment activities were not measured. In F_0 males, plasma cholinesterase activity was significantly (p \leq 0.01) reduced in the mid- and high-

dose groups as compared to controls with percent inhibition (%I) 21 and 54%, respectively. High-dose F₀ males also had significantly (p \leq 0.01) reduced RBC activity (%I = 32). Mid- and high-dose F_0 females had significantly (p \leq 0.01) reduced plasma activity (%I = 43 and 76, respectively) while high-dose F_0 females also had significantly (p \leq 0.01) reduced RBC (%I = 57) and brain (%I = 68) activities. Plasma activity was significantly (p \leq 0.01) reduced in all treated F_1 male groups as compared to controls (%I = 28, 30, and 62, respectively). Mid- (p \leq 0.05) and high-dose (p ≤ 0.01) F₁ males also had significantly reduced RBC activity (%I = 11 and 42, respectively). Mid- and high-dose F_1 females had significantly (p ≤ 0.01) reduced plasma activity (%I = 47 and 80, respectively) while high-dose F₁ females also had significantly (p \leq 0.01) reduced RBC and brain activities (%I = 63 and 51). The 51-68% inhibition of brain ChE activity in females in the high-dose (900 ppm) group indicates that dosing was conducted at an adequately high level; higher doses would likely yield an unacceptable level of mortality.

Therefore, the LOAEL for cholinesterase inhibition is 25 ppm (2.3 mg/kg/day; LDT) based on inhibition of plasma enzyme activity in F_1 males. The cholinesterase inhibition NOAEL was not identified.

No statistically significant differences occurred for absolute body weights, body weight gains, or food consumption of the F_0 or F_1 females during gestation or lactation for any treated group as compared to controls. High-dose F_0 males and females had low fertility indices with only 21 of 28 males siring litters and only 24 of 28 females becoming pregnant. However, this effect was not repeated in the F_1 generation. There were no statistically significant differences between treated and control groups for number of litters or pups/litter during lactation of either generation. Survival and viability of the F_1 pups was similar between treated and control groups. However, survival was greatly reduced in the high-dose F_2 pups with overall (day 0-21) survival only 61%. This was due mainly to a low viability index of 74% for lactation days 0-4.

Therefore, the LOAEL for reproductive toxicity is 900 ppm (93.2 mg/kg/day; HDT) based on reduced F_2 pup survival. The corresponding NOAEL for reproductive toxicity is 150 ppm (15.4 mg/kg/day; MDT).

This study is classified as Acceptable/Guideline and does satisfy the guideline requirement for a reproduction study (§83-4) in rats.

f. Mutagenicity

The available studies clearly indicate that bensulide is not genotoxic. Additionally, the negative mutagenicity studies support the lack of an oncogenic effect in the rat and mouse long-term feeding studies and also the absence of significant reproductive or developmental toxicity attributable to a mutagenic mode of action (i.e., decreased total implants, increased resorptions). Based on the overall results, there is no concern for mutagenicity.

The submitted test battery satisfies the new mutagenicity initial testing battery guidelines; therefore, no Category III study or additional further testing is required at this time.

(1) GLN 84-2/Mutagenicity (Category I)

In a reverse gene mutation assay in bacteria (MRID 00153493), strains TA98, TA100, TA1535, and TA1537 of S. typhimurium were exposed to bensulide technical (92.9% a.i.) at concentrations of 0 (dimethyl sulfoxide solvent control; DMSO), 0.005, 0.014, 0.041, 0.123, 0.370, 1.111, 3.333, 10.000, 25.000, or 50.000 μ L/plate (TA100) or 0 (DMSO), 0.037, 0.111, 0.333, 1.000, or 3.000 μ L/plate (TA98, TA1535, and TA1537) in the presence and absence of mammalian metabolic activation (metabolic activation mixture containing the S9 fraction from livers of Aroclor 1254-induced Sprague-Dawley rats).

Bensulide technical was tested up to and above levels at which it precipitated onto the culture medium (\geq 0.041 µL/plate for TA100; \geq 1.000 µL/plate for TA98, TA1535, and TA1537). The positive controls did induce the appropriate responses in the corresponding strains. There

was no evidence of induced mutant colonies over background.

This study is classified as Acceptable/Guideline. It does satisfy the requirement for Guideline 84-2 for <u>in vitro</u> mutagenicity (bacterial reverse gene mutation) data.

(2) GLN 84-2/Mutagenicity (Category I)

In a mammalian cell gene mutation assay (TK locus; MRID 43273901), mouse lymphoma L5178Y cultured cells cultured in vitro were exposed to bensulide technical (92.4 \pm 0.5% a.i.; given in MRID 43919602) in dimethyl sulfoxide (DMSO) at concentrations of 8, 14, 16, 21, 24, 28, 32, 35, 40, or 42 µg/mL in the absence and at 16, 24, 28, 32, 35, 40, 42, 48, 49, or 56 µg/mL in the presence of mammalian metabolic activation (S9 fraction containing homogenate from Aroclor 1254-induced rat liver).

Bensulide technical was tested up to cytotoxic concentrations, based on preliminary cytotoxicity assays demonstrating significant cytotoxicity at doses near 30 µg/mL and total cell death at doses as low as 25-30 µg/mL. There was no evidence of induced forward mutation at the TK locus over solvent control values at any dose tested.

This study is classified as Acceptable/Guideline. It does satisfy the requirement for Guideline 84-2 for <u>in vitro</u> mutagenicity (gene mutation in mammalian cells) data.

(3) GLN 84-2/Mutagenicity (Category II)

In a C57BL/6JfCD-1/Alpk mouse bone marrow micronucleus assay (MRID 41902602), 5 animals/sex/dose were treated with a single oral (gavage) dose of bensulide technical (92.7% a.i.) in corn oil (vehicle) at doses of 250 or 400 mg/kg (constant dose volume of 10 mL/kg). Bone marrow cells were harvested at 24, 48 and 78 hours post-treatment.

There were no signs of toxicity during the study. Bensulide technical was tested at an adequate dose, since the 400 mg/kg dose level (HDT) was selected based on the

results of a preliminary acute toxicity study (2 animals/sex/dose) in which mortalities were observed at doses of 500 mg/kg or greater, but not at 400 mg/kg or less. The positive control (cyclophosphamide) induced the appropriate response. There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time.

This study is classified as Acceptable/Guideline. It does satisfy the requirement for Guideline 84-2 for <u>in vivo</u> mutagenicity (mouse bone marrow micronucleus) data.

g. General Metabolism (85-series guidelines)

(1) GLN 85-1/Metabolism and Pharmacokinetics

In a metabolism study (MRIDs 42007901-42007904), bensulide technical, labelled with ¹⁴C in the phenyl ring (> 96.4% radiopurity; 925 MBq/mMole) was dissolved in corn oil (vehicle) and administered to Sprague-Dawley rats (5/sex/group; 7-8 weeks of age; 185-235 g body weight) following three treatment regimes. Animals in Group I received a single oral dose of radioactive bensulide at 1 mg/kg of body weight. Animals in Group II received 14 consecutive doses (1 mg/kg/day) of non-radioactive bensulide technical (99% a.i.) in corn oil, followed by a 1 mg/kg dose of radiolabelled bensulide technical in corn oil on day 15. Group III animals received a single oral dose of radiolabelled bensulide technical at 100 mg/kg of body weight. An additional group of animals (Group IV; 3/sex/group) were given a single oral dose of radiolabelled bensulide technical at 1 mg/kg of body weight and were subsequently used for autoradiological radiolabelled carbon dioxide release determinations. Administration by gavage was used for all treatment groups, and the volume of the corn oil and bensulide technical solution was kept at a constant of 4mL/kg of body weight.

For animals in Groups I-III, urine and feces were collected at 12, 24, 36, and 48 hours post-dosing and at 24-hour intervals thereafter until 7 days after dosing with radioactive bensulide. All animals in Groups I-III were sacrificed 7 days after treatment with radioactive bensulide

technical, and the following organs were removed and assayed for radioactivity: blood, liver, kidneys, muscle, fat lungs, uterus, heart, bone, spleen, thyroid, salivary glands, brain, adrenals, ovaries, testes, pancreas, gastrointestinal tract (stomach, small and large intestines, and caecum) and its contents, and the residual carcass. Radioactivity was determined by tissue combustion and/or liquid scintillation counting. For Groups IV animals, two rats of each sex were used for the autoradiography study and 1 rat of each sex was used or the carbon dioxide study.

In the autoradiography study, animals were sacrificed with Halothane at 24 hours after dosing with radioactive bensulide technical. The animals were then immediately frozen in a mixture of hexane and solid carbon dioxide. Each frozen carcass was embedded in a block of 2% carboxymethyl cellulose, and longitudinal sagittal section of about 20 µM thickness were cut and representative sections freeze-dried and subjected to autoradiography. In the carbon dioxide study, ¹⁴C-radiolabelled derived from the metabolism of radioactive bensulide technical and present in expired air was collected by passing the air through a 2N NaOH solution at 6, 12, 24, 36, and 48 hours after dosing.

The major route of excretion was via the urine, with peak urinary excretion of ¹⁴C-bensulide equivalents occurring between 0 to 24 hours for males and females in the low-dose group (Group I; 1 mg/kg) and in the high-dose group (Group III; 100 mg/kg). In Group I, total urinary excretion of 7 days after administration of radioactive bensulide technical accounted for 70 and 75 percent of the administered dose in males and females, respectively. Of these totals, 57 and 72 percent were excreted during the first 24 hours after dosing for males and females, respectively. In Group III, total urinary excretion accounted for 75 and 87 percent of the administered dose in males and females, respectively. Of these totals, 64 and 76 percent were excreted during the first 24 hours after dosing for males and females, respectively. For Group II (prior 14-day administration of non-radioactive bensulide technical before radioactive bensulide administration, both at 1 mg/kg), total urinary excretion of radioactivity over 7 days past dosing with radioactive bensulide accounted for 79 and 88 percent

of the administered dose in males and females, respectively. Of these totals, 63 and 83 percent were excreted during the first 24 hours after dosing for males and females, respectively. For Group IV, urinary excretion of ¹⁴-C radioactivity derived from bensulide technical over a 48-hour period accounted for 67% for one male and 86% in one male.

For Group I, total fecal excretion of radioactivity derived from ¹⁴C-bensulide technical over 7 days postdosing accounted for 22 and 20 percent of the administered dose in males and females, respectively. Of these totals, 18 percent was excreted during the first 24 hours for both males and females. For Group III, total fecal elimination over 7 days post-dosing of bensulide-derived radioactivity accounted for 22 and 11 percent of the administered dose for males and females, respectively. Of these totals, 20 and 8 percent were excreted during the first 24 hours after dosing for males and females, respectively. In Group II animals, total fecal excretion of radioactivity over 7 days post-dosing accounted for 14 and 8 percent of the administered dose for males and females, respectively. Of these totals, 9 and 6 percent were excreted during the first 24 hours post-dosing for males and females, respectively. In Group IV, fecal excretion of radioactivity over 48 hours post-dosing accounted for 12% of the administered dose in one male and 7% in one female.

The amount of residual radioactivity in all organs/tissues except for the liver (0.02 to 0.21% of the dose) from all rats was low at 7 days after single oral administration of radioactive bensulide technical. The radioactivity found in the carcasses and in other tissues accounted for 0.3% to 2.5% and less than 0.1% of the administered dose, respectively. The highest concentration of radioactivity was found in whole blood. The majority of the radioactivity in the blood was associated with the cellular component. In general, less well perfused tissues showed lower concentrations of radioactivity. Whole body autoradiography of rats killed 24 hours after dosing showed that, in male rats, the majority of the radioactivity was present in the blood, lung, spleen, bone marrow, and the glandular part of the stomach, the contents of the intestines,

and in the intestinal walls. Moderate amounts of radioactivity was found in the liver, kidney, salivary glands, the capsule of the seminal vesicles, nasal passages and the white matter of the brain. The intensity of radioactivity in the female rats was much lower than in the male rats.

In a biotransformation study (MRID 42225401), bensulide metabolites were quantitated and identified in rat urine and fecal extracts from previous studies (MRID 42007901-42007903). To obtain sufficient material to confirm metabolite identities, four successive daily doses of 50 mg [14C]-bensulide/kg were administered to 5 Sprague-Dawley female rats (bulk collection experiment; 99% a.i., unlabeled, Batch No. Y06379/006; >98.0% a.i., [14C]-labeled, Batch No. Y06379/005). Biliary excretion was assessed in one male and one female rat with cannulated bile ducts given an oral dose of 100 mg [14C]-bensulide/kg.

No animals died before scheduled sacrifice in either experiment. In the bulk collection experiment, 52.5% of the administered dose was recovered in the urine and 16.3% in the feces. In cannulated rats, a substantially higher fraction of the given dose was in the feces (40.9% in the male, 68.6% in the female), possibly due to poor intestinal wall absorption. Biliary excretion was minimal (5-6% of dose) and biliary metabolites were not analyzed; the mass balance accounting was acceptable (109.2%-114.4%).

Bensulide metabolites found by TLC in excreta from previous studies accounted for about 59-78% of the administered dose in the urine and about 2.5-8.3% in the feces, distribution varying with sex and dose. Four metabolites were identified. Metabolite I was the most abundant in the urine for all doses in both sexes (26-58% of given dose) whereas in fecal extracts, Metabolites I, II, or IV predominated (each 0.25-3.4% of dose). Unidentified metabolites individually represented < 3% of the dose except urinary metabolite "H" (\leq 16.1% of dose) and one fecal metabolite (TLC spot 6; \leq 6.23% of dose). Metabolite I and II formation is proposed to involve cleavage of the PO₂[CH(CH₃)₂]₂ moiety of bensulide, followed by methylation and oxidation of the sulphur atom. Conjugation with glycine

or carboxylation and oxidative desulphuration is proposed to lead to Metabolite III and IV formation, respectively.

This study is classified acceptable/guideline. It was intended to satisfy the guideline requirement for a metabolism study (§85-1) in rats together with four previous studies (MRIDs 42007901-42007904). Together these metabolism studies satisfy the Guideline (§85-1) requirements for metabolism data for bensulide technical in rats.

h. Neurotoxicity

(1) GLN 81-7/Delayed Neurotoxicity in the Hen

In an acute delayed neurotoxicity study (MRID 43334302), Bensulide (tech., 92.4% a.i.) was assessed using groups of 15 single comb white leghorn laying hens (Gallus gallus domesticus) given a single neat gavage dose of Bensulide (2000 mg a.i./kg nominal dose; actual dose was 2262 mg/kg in a dosing volume of 2 mL/kg). An acute oral toxicity study (43306301) determined an LD₅₀ of 3221 mg/kg for Bensulide in the domestic laying hen. Positive controls (12 birds) were given 800 mg TOCP/kg and 12 birds given corn oil served as vehicle controls. Three birds of each group were sacrificed at ~48 hrs for activity analysis of neurotoxic esterase (NTE) in brain and spinal cord and acetylcholinesterase (AChE) in brain. Behavior assessments (locomotor ability) were conducted on nine birds from both control groups and 12 birds from the Bensulide group over a period of 21 days. Pathology (brain, spinal column and peripheral nerves) was evaluated in all remaining animals at Day 21.

Based on the study results, Bensulide did not induce acute delayed neurotoxicity in the domestic laying hen at the dose tested. NTE activity was not affected by treatment. A non-significant decrease of ~24% was observed for brain cholinesterase in treated hens.

This study meets the requirements of § 81-7 and is classified as Acceptable/Guideline because, although animals were not tested at the LD_{50} and no signs of

neurotoxicity were observed, animals were tested at the limit dose of 2 g/kg.

(2) GLN 81-8ss/Acute Neurotoxicity in the Rat

In an acute neurotoxicity screening study (MRID 43195901), 22 CD rats/sex/group were administered single gavage doses of 0, 30, 100 or 300 mg bensulide (tech., 92.4% a.i.)/kg (males) or 0, 15, 50 or 150 mg/kg (females) in 5 mL/kg corn oil. Functional observational battery (FOB) and motor activity tests were conducted on 12 rats/sex/dose pretreatment, on the day of dosing (day 0) and days 7 and 14 post-dosing. Plasma, erythrocyte and brain cholinesterase (ChE) activities were measured from 5 rats/sex at pretreatment, day 0 (6.25 and 6.75 hrs post-dosing) and day 15. Six perfused control and high dose rats/sex were evaluated for neuropathology.

At 150 mg/kg (females only), an increased incidence of diarrhea, flaccid abdominal and/or body tone (all 6/12 vs. 1, 2 and 2, controls) and pinpoint pupils (3/12 vs 0, controls) were observed on Day 0 in the FOB. At 300 mg/kg (males only), one death occurred on Day 1, preceded by clinical signs (salivation, lacrimation/ocular discharge, decreased respiration, hypothermia, and fur staining on muzzle and ventral surface). A second male exhibited abnormal respiration, tremors, hypoactivity, dehydration and fur staining between Days 1-3. In the FOB, increased incidence of decreased arousal and locomotor activity (for both, 7/12 vs. 3, controls) were observed. A slight but statistically significant depression of body weight (-6.6%) was also observed on Day 7. No treatment-related effects on motor activity or macroscopic/microscopic neuropathology were reported. The LOAEL is 150 mg/kg, based on minimal, transient clinical signs consistent with cholinesterase inhibition in females. The NOAEL is 100 mg/kg.

At 50 mg/kg (females only), plasma ChE was decreased on day 0 by 80% less than controls (not significant). At 100 mg/kg (males only), plasma ChE was decreased on day 0 by 53% (not significant). At 150 mg/kg (females only) on day 0, reductions were observed in

plasma ChE (89% less than controls, p<0.01) and erythrocyte ChE (37% less than control, p<0.01) both of which showed partial recovery by day 15. However, a significant decrease (73% of control, p<0.01) in brain ChE for high-dose females was noted on day 15 which was not present at day 0 (18% less than controls, not significant). At 300 mg/kg (males only), statistically significant ChE inhibition was observed only in the high-dose groups. On day 0, there were significant decreases in brain ChE (62% of control, p<0.01), plasma ChE (19% of control, p<0.01), and erythrocyte ChE (60% of control, p<0.01) for males of the high dose (300 mg/kg) group. At day 15, brain ChE was still significantly reduced (73% of control, p<0.01) but values for plasma and erythrocyte ChE had returned to normal.

The plasma ChE inhibition LOAEL is 50 mg/kg, based on 80% inhibition (no p) of plasma cholinesterase activity in females on Day 0. The plasma ChE NOAEL is 15 mg/kg.

The RBC ChE inhibition LOAEL is 150 mg/kg, based on 37% inhibition (p \le 0.01) of RBC ChE activity in females on Day 0. The RBC ChE NOAEL is 50 mg/kg.

The brain ChE inhibition LOAEL is 150 mg/kg, based on 18% inhibition (no p) of brain ChE activity in females on Day 0 and 27% inhibition (p \leq 0.01) on Day 15. The brain ChE NOAEL is 50 mg/kg.

This study is classified as Acceptable/Guideline and satisfies the guideline requirement for an acute neurotoxicity study in rats (§81-8ss).

2. Dose/Response Assessment

a. Special Sensitivity to Infants and Children

The toxicity database for bensulide and other organophosphates was evaluated in regard to the sensitivity of infants and children by the FQPA Safety Factor Committee (Brenda Tarplee and Jess Rowland Report, 8/6/98). The Committee took the following into consideration:

Adequacy of the data base: The toxicology data base on bensulide includes an acceptable two-generation reproduction study in rats (MRID 43948701) and acceptable prenatal developmental toxicity studies in rats (MRID 00146585) and rabbits (MRID 00152845). The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals. These studies meet the data requirements for a food-use chemical as defined by 40 CFR Part 158. No data gaps were identified.

Susceptibility issues: In the two-generation reproduction study in rats, cholinesterase inhibition (ChEI) in the adult animals was observed at a dose which produced no evidence of toxicity in the offspring (the parental plasma ChEI NOAEL was <2.3 mg/kg/day, while the offspring NOAEL was 15.4 mg/kg/day, based on decreased viability in second generation pups at 93.2 mg/kg/day, the highest dose tested). Although bensulide elicited decreased viability in second generation pups at the highest dose tested in the reproduction study, there was significant inhibition of maternal brain cholinesterase activity at this dose level.

In both the prenatal developmental toxicity studies in rats and rabbits, developmental toxicity was not observed up to the highest dose tested, although evidence of systemic toxicity was demonstrated in the maternal animals, including body weight decrements in both species and tremors, decreased food consumption, increased liver weights, and cholinesterase inhibition in rats.

The FQPA Safety Factor Committee determined that since there was no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats, the additional 10x factor as required by FQPA should be **removed**.

The FQPA Safety Factor Committee also determined that a developmental neurotoxicity study was not required for bensulide.

b. Carcinogenic Classification and Risk Quantification

The Health Effects Division Hazard Identification Assessment Review Committee met on July 10, 1997, to discuss and evaluate the oncogenicity data base in support of bensulide reregistration and to reassess the cancer classification of this chemical. The Committee classified Bensulide as a "Group E" substance, indicating evidence of non-carcinogenicity for humans; i.e., the chemical is not likely to be carcinogenic in humans via relevant routes of exposure. This weight of the evidence judgement is largely based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies (rat: MRID Nos.: 43919602, 44161101, 44161102, 44161103, and 44206301; mouse: MRID Nos.: 44161102, 44161103, 44161104, 44161105, and 44206301). This classification is also supported by the lack of mutagenic activity (MRIDs 00153493, 41902601, 41902602, 42479201, 43273901, 470065014, 470065015, and 470065016). It should be noted, however, that designation of an agent as being in Group E is based on the available evidence and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

c. Developmental Classification

Bensulide has been shown to elicit no developmental effects at the highest doses tested in studies in both rats (95 mg/kg/day; MRID 00146585) and rabbits (80 mg/kg/day; MRID 00152845). Therefore, it is not regarded as a developmental toxicant.

d. Dermal Absorption

There are no dermal absorption studies with bensulide. A dermal absorption value is not needed for short- and intermediate-term dermal exposure because the endpoint is from a dermal exposure study; there are currently no long-term dermal exposure scenarios. If a need for a dermal exposure value develops, the Hazard Identification Assessment Review Committee has calculated a dermal absorption value of 10% by comparing body weight changes and clinical signs occurring in the developmental rat study to the 21-day dermal rat study (Brenda Tarplee and Jess Rowland Report, 2/24/99).

e. Toxicological Endpoints

A summary of the toxicological endpoints chosen for risk assessments of exposure to bensulide for various time periods by appropriate routes of exposure is presented in Table 3.

Table 3. Toxicological Endpoints for Human Risk Assessments with Bensulide

EXPOSURE	DOSE	ENDPOINT	STUDY								
Acute RfD	NOAEL = 15 mg/kg/day	Plasma ChE Inhibition	Acute Neurotoxicity - Ra								
		,									
Chronic RfD	NOAEL = 0.5 mg/kg/day	Plasma, Brain ChE Inhibition. Decreased Body Weight Gain.	Chronic - Dog								
	UF =100 Chronic RfD = 0.005 mg/kg/day										
Short-Term Dermal	NOAEL = 50 mg/kg/day	Plasma, Brain ChE Inhibition	21-Day Dermal Study - Rat								
Intermediate- Term Dermal	NOAEL = 50 mg/kg/day	Plasma, Brain ChE Inhibition	21-Day Dermal Study - Rat								
Long-Term Dermal ^a	Oral NOAEL = 0.5 mg/kg/day	Brain, Plasma ChE Inhibition. Decreased Body Weight Gain.	Chronic - Dog								
Short-Term Inhalation ^b	Oral NOAEL = 5.5 mg/kg/day	Maternal Plasma ChE Inhibition	Developmental - Rat								
Intermediate- Term Inhalation ^b	Oral NOAEL = 0.5 mg/kg/day	Plasma ChE Inhibition. Decreased Body Weight Gain.	Chronic - Dog								
Long-Term Inhalation ^b	Oral NOAEL = 0.5 mg/kg/day	Brain, Plasma ChE Inhibition. Decreased Body Weight Gain.	Chronic - Dog								

^a 10% Dermal Absorption assumed for long-term dermal exposure if applicable.

MOE = 100 for dermal and inhalation risk assessments.

^b 100% absorption for inhalation exposure is assumed.

3. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure (Food Sources)

(1) GLN 860.1200: Directions for Use

A Reference Files System (REFS) search, conducted on 05/16/97, identified two bensulide end-use products (EPs) registered under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3 to Gowan Company, with registered uses on food/feed crops. These EPs, including the associated Special Local Need (SLN) registrations under FIFRA Section 24 (c), are listed in Table 4.

For the purpose of generating this Residue Chemistry Science Chapter, HED examined the registered food/feed use patterns and reevaluated the available residue chemistry database for adequacy in supporting these use patterns.

Table 4: Bensulide EPs with Food/Feed Uses Registered to Gowan Company

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
10163-200 ¹	04/16/97	4 lb/gal EC	Prefar® 4-E Selective Herbicide
10163-222 ²	04/16/97	6 lb/gal EC	Prefar® 6-E Selective Herbicide

¹Including SLN Nos. AZ940001, ID930008, OR940023, and WA940010.

(2) GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in carrots, lettuce, and tomatoes have been submitted and evaluated. The cottonseed metabolism study requested in the Phase 4 Review is no longer required because cotton has been removed from the registrant's product labels. The bensulide residues of concern are those that are currently regulated, bensulide and bensulide oxygen analog (see Figure 1).

²Including SLN Nos. CA970001 and OR960040.

Figure 1. Chemical Names and Structures of Bensulide Residues of Concern in Plant Commodities

Common Name Chemical Structure Chemical Name	Common Name Chemical Structure Chemical Name
Bensulide O H S OCH(CH ₃) ₂ OCH(CH ₃) ₂ OCH(CH ₃) ₂	Bensulide oxygen analog O O H S O O N S O O CH(CH ₃) ₂ O O O O O O O O O O O O O O O O O O O
S-(O,O-diisopropyl phosphorodithioate) ester of N-(2-mercaptoethyl)benzenesulfonamide	S-(O,O-diisopropyl phosphorothioate) ester of N- (2-mercaptoethyl)benzenesulfonamide

(3) GLN 860.1300: Nature of the Residue - Livestock

Data pertaining to the nature of the residue in animals are not required. The only livestock feed item associated with registered bensulide uses is carrot culls, and product labels currently bear a restriction against the feeding of treated carrots to livestock. Although the Agency normally does not support this type of feeding restriction, HED has allowed this restriction because use of bensulide on carrots is limited to TX and low residues are present on carrots. HED reserves the right to require livestock metabolism studies if the registrant requests registration of additional uses of bensulide.

(4) GLN 860.1340: Residue Analytical Methods

Adequate methods are available for data collection and tolerance enforcement for plant commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a gas-liquid chromatographic (GC) method (Method I), using either phosphorus-sensitive thermionic detection or flame photometric detection, for the determination of bensulide and bensulide oxygen analog in plant commodities. A thin-layer chromatographic (TLC) method (Method A) is available for confirmation. Method I uses benzene as a solvent. Methods used for data collection were modifications of Method I with the substitution of toluene for benzene.

HED had previously reserved the requirement for independent laboratory validation of a new enforcement method [high-pressure liquid chromatographic (HPLC) method] pending determination of bensulide residues of concern. Because HED determined that bensulide residues of concern are those that are currently regulated, no new enforcement method, and therefore no independent laboratory validation, is required.

(5) GLN 860.1360: Multiresidue Methods

The 2/97 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that bensulide is completely recovered (>80%) using Multiresidue Methods Sections 302 (Luke Method; Protocol D) and 304 (Mills Method; Protocol E, fatty foods) and partially recovered (70%) using Section 303 (Mills, Onley, Gaither Method; Protocol E, non-fatty foods). No information regarding the recovery of bensulide oxygen analog using Multiresidue Methods is included in the PESTDATA database.

(6) GLN 860.1380: Storage Stability Data

The final results of an ongoing 3-year storage stability study have been submitted. The reregistration requirements for storage stability data are fulfilled for the following commodities with existing tolerances for bensulide: carrots, onions (dry bulb), cucurbits, leafy vegetables, and bell peppers. Data are also available to support tolerances proposed for Brassica (cole) leafy vegetables. There are no currently registered uses of bensulide on cotton; therefore the tolerances should be revoked, and storage stability data to support the tolerance are not required.

The final storage stability data indicate some degree of instability of residues of bensulide *per se* in/on selected raw agricultural commodities (RACs) under frozen storage conditions. Residues of bensulide *per se* were demonstrated to be stable for up to 6 months in/on cabbage and cucumber, and for less than 3 months in/on broccoli and leaf lettuce. Residues of bensulide *per se* declined by 55-61% in/on broccoli after 12 months and by 51-53% in

cabbage, 43-46% in/on cucumber, and 57-59% in/on leaf lettuce after 36 months.

Based on previously submitted storage stability data reviewed under Phase IV, bensulide *per se* has been demonstrated to be stable for a period of three years in alfalfa, almonds, apples, corn, oranges, peppers, potatoes, soybeans, and wheat. Storage stability data from potatoes have been translated to cover carrots. Similarly, storage stability data from peppers have been translated to cover tomatoes.

Residues of bensulide oxygen analog are relatively stable in/on broccoli and onions for up to 12 months, and in/on cabbage, carrots, cucumbers, lettuce (leaf), and bell peppers for up to 36 months.

The storage conditions and intervals of the field trial samples for representative commodities have been submitted. HED has taken into consideration the results of the available storage stability data during the conduct of tolerance reassessment.

(7) GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on all raw agricultural commodities (RACs) except non-bell peppers have been fulfilled. The registrant must either restrict use to bell peppers or perform three geographically representative field trials on non-bell peppers. Adequate field trial data depicting bensulide residues of concern following treatments according to the maximum registered use patterns have been submitted for all RACs. Refer to the "Tolerance Reassessment Summary" for recommendations regarding appropriate tolerance levels. Label revisions are required for some crops in order to reflect current Agency policies and/or to reflect the parameters of use patterns for which field trial data are available; see "GLN 860.1200: Directions for Use."

Although Gowan currently has no registered uses of bensulide on tomatoes, the registrant had previously proposed to retain the tomato tolerance for import purposes.

In order to determine whether the established tolerance is adequate to cover bensulide residues of concern in/on imported tomatoes, the registrant must submit copies of product labels with English translations from all countries from which bensulide-treated tomatoes may be imported into the U.S. In addition, twelve tomato crop field trials must be conducted in Mexico to support a tolerance with no U.S. registrations, i.e., use on imported tomatoes. If the registrant wishes to register domestic use of bensulide on tomatoes, the available field trial data would support a use pattern identical to the registered use pattern on peppers.

No additional field trial data are required for cotton because there are currently no registered uses of bensulide on this crop. In addition, no field trial data are required to support use of bensulide on grass grown for seed because this use has been deleted from product labels.

(8) GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of imported tomatoes will be fulfilled if a tomato processing study presently under review is found acceptable. No additional data are required for cottonseed processed commodities because there are currently no registered uses of bensulide on cotton.

(9) GLN 860.1480: Meat, Milk, Poultry, Eggs

Data pertaining to the magnitude of the residue in meat, milk, poultry, and eggs are not required. The only livestock feed item associated with registered bensulide uses is carrot culls, and product labels currently bear a restriction against the feeding of treated carrots to livestock. Although the Agency normally does not support this type of feeding restriction, because use of bensulide on carrots is limited to TX (produces about 4% of the U.S. carrot crop) and low residues are present on carrots, HED has allowed this restriction. HED reserves the right to require livestock feeding studies if the registrant requests registration of additional uses of bensulide.

(10) GLN 860.1400: Water, Fish, and Irrigated Crops

Bensulide is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

(11) GLN 860.1460: Food Handling

Bensulide is presently not registered for use in foodhandling establishments; therefore, no residue chemistry data are required under this guideline topic.

(12) GLNs 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The reregistration requirements for accumulation in rotational crops are fulfilled. An adequate confined rotational crop study has been submitted and evaluated. HED concluded that no limited field trials or rotational crop tolerances would be required, provided that a 120-day plantback interval is established for rotational crops. Limited field rotational crop trials would be required to support plantback intervals of less than 120 days. Currently, all product labels bear a plantback interval of 120 days for all crops not included on the label.

(13) Tolerance Reassessment Summary

Tolerances for residues of bensulide in/on plant commodities [40 CFR §180.241] are presently expressed in terms of the combined residues of bensulide and its oxygen analog. Following evaluation of plant metabolism studies, HED has determined that the bensulide residues that warrant regulation in plant commodities are those which are currently regulated. HED notes that the chemical name for the bensulide oxygen analog in the entry under 40CFR §180.241 is incorrect. The correct name [S-(O,O-diisopropyl phosphorothioate) ester of *N*-(2-mercaptoethyl)benzenesulfonamide] should be entered.

A summary of bensulide tolerance reassessments is presented in Table 5.

Tolerances Listed Under 40 CFR §180.241

Adequate data are available to reassess the established tolerances for the following commodities, **as defined**: cucurbits, carrots, bell peppers, leafy vegetables, and onions (dry bulb). The phrase "negligible residues" should be removed from bensulide tolerance definitions. HED recommends that tolerances for the following commodities: curcurbits, and leafy vegetables be revised from 0.1 ppm to 0.15 ppm to account for the instability of bensulide <u>per se</u> in/on these commodities as evidenced in a nonconcurrent storage stability study. This recommendation was agreed upon by HED's Chemistry Science Advisory Council at a meeting held on September 8, 1997.

Based on the storage intervals for various crops and the stability data submitted, HED believes that residues of bensulide oxon were stable during the given storage periods prior to analysis. Based on these same data, HED has determined that residues of bensulide *per se* are unstable in a variety of crops. In general, an approximate loss of 50% of the initial residues of bensulide *per se* could be expected across a variety of crops.

The Agency has taken into consideration the results of the available storage stability data during tolerance reassessment, and concluded that in order to account for potential residue losses during storage prior to analysis, the tolerance for bensulide residues should be increased from 0.10 ppm [based on non-detectable levels of bensulide *per* se (0.05 ppm) plus bensulide oxon (0.05 ppm)] to 0.15 ppm (based on twice the limit of detection for bensulide *per* se (0.10 ppm) plus the limit of detection for bensulide oxon (0.05 ppm)) for the following commodities or crop groups: curcurbits, leafy vegetables, Brassica (Cole) leafy vegetables group.

Residues of bensulide and bensulide oxon were stable in carrots (data translated from potatoes), onions, and bell peppers during the periods of storage prior to analysis. Therefore, tolerances for these commodities are based on field trial data that has not been corrected for residue losses during storage.

Note that the tolerance for onions (dry bulb) will cover uses on garlic and shallots. In addition, the established tolerance for carrots must be revised to a tolerance with regional registration.

The established tolerance for cottonseed should be revoked because there are currently no registered uses of bensulide on cotton.

Tolerances To Be Proposed Under 40 CFR §180.241

A tolerance must be proposed for the Brassica (cole) vegetables group. An appropriate level for this tolerance has been determined that reflects storage stability considerations. The Agency recommends the registrant propose a tolerance of 0.15 ppm.

Table 5: Tolerance Reassessment Summary for Bensulide.

Commodity Current Tolerance, ppm Tolerance ppm¹		Reassessment,	Comment/ [Correct Commodity Definition]				
	Tolerances Listed Under 40 CFR §180.241						
Carrots	0.1	This tolerance must be modified to one with region registration (TX).					
Cottonseed	0.1	Revoke There are currently registered uses of bens cotton.					
Cucurbits	0.1	0.15	[Cucurbit Vegetables Group]				
Fruiting Vegetables	0.1	0.10	[Fruiting Vegetables (except cucurbits) Group]				
Leafy vegetables	0.1	0.15 [Leafy Vegetables (e. Brassica Vegetables)					
Onions (dry bulb)	/ bulb) 0.1 0.10						
Tolerances to be Proposed							
Brassica (Cole) Leafy Vegetables Group		0.15 ²	[Brassica (Cole) Leafy Vegetables]				

¹Existing tolerances have been reassessed in light of the submitted 3-year storage stability study for bensulide and bensulide oxon.

 $^{2}\mbox{The registrant}$ should propose a tolerance of 0.15 ppm for Brassica (Cole) Leafy Vegetables.

(14) Codex Harmonization

There are no Codex Maximum Residue Limits (MRLs) established for bensulide. Therefore, there are no issues of compatibility between U.S. tolerances and Codex MRLs.

b. Dietary Risk Assessment and Characterization

(1) Dietary Exposure Assumptions

Previous dietary risk analyses for bensulide were conducted with the Dietary Risk Evaluation System (DRES) and used consumption data from the 1977-78 National Food Consumption Surveys. Although exposures were below HED's level of concern, newer tools, Dietary Exposure Evaluation Model (DEEM™) and updated consumption data are now available, and therefore revised acute and chronic dietary exposure and risk analyses were calculated for bensulide. FDA monitoring data were also incorporated into the revised acute dietary assessment. There were no monitoring data from USDA's Pesticide Data Program.

The bensulide acute and chronic dietary exposure and risk estimates generated using DEEM™ are significantly below the HED's level of concern and are relatively similar to the DRES estimates (when results at similar tiers of analysis are compared). The dietary assessments are described in more detail below and results are shown in Table 6.

DEEM™ incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For the acute dietary risk assessment with bensulide, the entire distribution of single day food consumption events was combined with a single residue level (deterministic analysis, risk at 95th percentile of exposure reported) to obtain a distribution of exposure in mg/kg/day. For the chronic dietary risk assessment, the three-day average of consumption for each subpopulation was combined with residues in commodities to determine average exposure in mg/kg/day.

Reassessed tolerance-level residues were used in both the acute and chronic Tier 1 analyses, assuming 100 percent crop treated (%CT); reassessed tolerances are based on the

combined limits of quantitation (LOQs) for bensulide and its oxygen analog metabolite. Field trial data indicate detectable residues are not likely in raw agricultural commodities under the current use patterns. The chronic analysis was refined with weighted average %CT data provided by the OPP Biological and Economic Analysis Division (BEAD).

Food and Drug Administration (FDA) surveillance monitoring data were collected for bensulide on numerous commodities (1992-1997). No bensulide residues were detected (<0.01 ppm) in any of the commodities analyzed, which included numerous RACs as well as juices, sauces, and some baby foods. In order to use monitoring data quantitatively in risk assessments, HED generally requires at least 100 samples of a given commodity.

The FDA surveillance data were used to refine the acute dietary risk assessment by using a residue of ½ the level of detection (0.005 ppm) for all commodities [but assuming 100 percent crop treated (%CT)]. It is noted that bensulide residues have never been detected in field trials. The FDA monitoring data could be used to refine the chronic dietary risk assessment. However, given the low chronic dietary risk estimated based on tolerance-level residues and incorporating percent crop treated information, HED determined that calculation of chronic anticipated residues from monitoring data is not warranted for bensulide.

An RfD which includes the FQPA safety factor is now referred to as the population adjusted dose (PAD). Since the HED FQPA Safety Factor Committee removed the 10X Safety Factor, the acute and chronic RfDs are identical to the acute and chronic PADs, respectively.

(2) Acute Dietary Exposure and Risk

Acute dietary exposure was determined assuming reassessed tolerance level residues and 100 %CT, corresponding to a Tier 1 acute analysis. Estimated dietary exposure was highest for children 1-6, with 1.8% of the acute RfD consumed at the 95th percentile of exposure; for the general US population, <1% of the aRfD was consumed. [The DRES software estimated an acute dietary risk of 6.7 %RfD (=%aRfD) for children 1-6, and 2.7 %RfD for the general US population]. Differences in

DRES and DEEM™ estimates are likely due to changes in consumption patterns. Incorporation of the ½ LOD residue values from FDA monitoring data, but assuming 100%CT resulted in acute dietary exposure/risk estimates of <1% aRfD for children 1-6 (0.08 %aRfD) and the general US population (0.04 %aRfD). Even though the refined residue estimates were used, HED has reported the acute dietary risk at the 95th percentile of exposure since a deterministic (rather than probabilistic) approach was used, and since 100 %CT was assumed for all commodities. In summary, acute dietary exposure and risk associated with bensulide uses supported through reregistration are considered to be negligible.

(3) Chronic Dietary Exposure and Risk

Chronic dietary exposure was determined assuming reassessed tolerance level residues; a second analysis was performed incorporating the weighted average of %CT provided by BEAD. Estimated chronic dietary exposure was highest for children 1-6, with 13% of the chronic RfD (cRfD) consumed; estimated dietary risk for the general US population was 7.1% cRfD. When the analysis was refined with %CT data, estimated chronic dietary risk was <1% cRfD for the general US population and all population subgroups (non-nursing infants were highest, at 0.8 %cRfD). [The DRES software (Tier 1 analysis) estimated a chronic dietary risk of 12.5%RfD (=%cRfD) for children 1-6, and 7.5% RfD for the general US population, which is essentially the same risk estimated using DEEMTM].

(4) Carcinogenic Risk

Bensulide is classified as a Group E chemical, indicating evidence of non-carcinogenicity for humans. (See HazID Committee Report, 7/31/97).

Table 6. Acute and Chronic Dietary Exposure and Risk Estimates for Bensulide.1								
Population Subgroup	Acute Dietary Exposure/Risk Reassessed Tolerances, 100%CT		Acute Dietary Exposure/Risk Monitoring Data Residues 100%CT		Chronic Dietary Exposure/Risk Reassessed Tolerances, 100%CT		Chronic Dietary Exposure/Risk Reassessed Tolerances, Weighted Ave. %CT	
	Exposure (mg/kg/day) 95th %-ile	%aRfD	Exposure (mg/kg/day) 95th %-ile	%aRfD	Exposure (mg/kg/day)	%cRfD	Exposure (mg/kg/day)	%cRfD
General US Population	0.001320	<1	0.000059	<1	0.000356	7.1	0.000015	<1
All Infants <1yr	0.001777	1.2	0.000073	<1	0.000342	6.8	0.000028	<1
Nursing Infants <1yr	0.000566	<1	0.000028	<1	0.000104	2.1	0.000002	<1
Non-Nursing Infants <1yr	0.001888	1.3	0.000071	<1	0.000442	8.8	0.000039	<1
Children (1-6 years)	0.002636	1.8	0.000122	<1	0.000660	13	0.000022	<1
Children (7-12 years)	0.001740	1.2	0.000081	<1	0.000478	9.6	0.000016	<1
Females, 13-19 years	0.001318	<1	0.000060	<1	0.000332	6.6	0.000011	<1
Females, 13-50 years	0.001025	<1	0.000049	<1	0.000308	6.2	0.000013	<1
Females, 20+ years	0.001099	<1	0.000045	<1	0.000301	6.0	0.000015	<1
Males, 13-19 years	0.001223	<1	0.000056	<1	0.000330	6.6	0.000011	<1
Males, 20+ years	0.001056	<1	0.000048	<1	0.000302	6.0	0.000013	<1

¹The acute population adjusted dose (aRfD) is 0.15 mg/kg/day; the chronic population adjusted dose (cRfD) is 0.005 mg/kg/day.

c. Drinking Water

(1) Calculation of Drinking Water Levels of Comparison

Based on environmental fate data, bensulide is very persistent but not mobile in soil. Monitoring data for bensulide were limited and could not be used quantitatively in risk assessments. Ground water modeling with SCI-GROW and surface water modeling with PRZM-EXAMS were used to calculate drinking water estimated concentrations which were then compared to drinking water levels of comparison (DWLOCs). The DWLOC is the maximum concentration in drinking water which does not exceed a level of concern when considered together with dietary exposure and was calculated with the following equations. Results are shown in Tables 7 and 8.

allowable water exposure = RfD - dietary exposure

DWLOC = water exposure x body wt consumption x 10^{-3} mg/ μ g

(2) Comparison of Chronic DWLOCs to Estimated Drinking Water Concentrations

The drinking water estimated concentration for surface water were greater than the chronic DWLOCs, indicating that chronic exposure to bensulide in drinking water might be of concern. When turf use was eliminated, the chronic DWLOCs were comparable to the drinking water estimated concentrations for surface water and were not of concern for adults, however concerns remained for infants and children. However, the estimated concentrations for water from modeling are conservative and are higher than expected to be actually found in drinking water. The drinking water estimated concentration for ground water was less than the chronic DWLOC and was not of concern.

Table 7. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (μg/L)¹	Surface Water (μg/L)²	DWLOC (μg/L)
U.S. Population	0.005	0.000015	0.004985	0.9	158/947	174
Females (13+, nursing)	0.005	0.000019	0.004981	0.9	158/947	150
Non-nursing Infants (<1 yr)	0.005	0.000039	0.004961	0.9	158/947	50

¹From SCI-GROW modeling.

(3) Comparison of Acute DWLOCs to Estimated Drinking Water Concentrations

The drinking water estimated concentrations for surface and ground water were less than the acute DWLOCs, indicating that acute exposure to bensulide is not a concern.

Table 8. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (μg/L)¹	Surface Water (μg/L) ²	DWLOC (μg/L)
U.S. Population	0.15	0.000059	0.149941	0.9	165/979	5248
Females (13-19)	0.15	0.000060	0.14994	0.9	165/979	4498
Children (1-6)	0.15	0.000122	0.149878	0.9	165/979	1499

¹From SCI-GROW modeling.

Population subgroups were the U.S. population (70 kg body weight), the female subgroup with the highest exposure (60 kg body weight), and the infant/child subgroup with the highest exposure (10 kg body weight). Water consumption was assumed to be 2 L for adults and 1 L for children and infants. The crop producing the highest modeled exposure in drinking water was used.

 $^{^2}$ Two values for surface water concentrations from PRZM-EXAMS modeling are reported. The value of 158 μ g/L is from vegetable application and the 947 μ g/L value is from turf use.

 $^{^2}$ Two values for surface water concentrations from PRZM-EXAMS modeling are reported. The value of 165 μ g/L is from vegetable application and the 979 μ g/L value is from turf use.

4. Occupational and Residential Exposure Risk Assessment and Characterization

This document addresses the exposures and risks associated with the use of the organophosphate herbicide, bensulide, that occur through non-dietary exposure. These exposures can occur as a result of applying bensulide or by entering areas that have been previously treated with bensulide. This chapter does not address possible bensulide exposures that occur through dietary intake of foods and water. Exposures can occur as a part of one's job or through uses of bensulide on residential lawns and other areas that are frequented by the general public. Occupational and residential exposures are addressed separately in this document.

Risk is defined in the U.S. EPA Guidelines for Exposure Assessment (U.S. EPA, Federal Register Volume 57, Number 104, Friday May 29, 1992) as the probability of deleterious health or environmental effects. Risk assessment can be described as the process that defines the risk. The risk assessment process has 4 major components including: exposure assessment, hazard identification, evaluation of the dose response, and characterization of the calculated risk values. This document address the exposure assessment and risk characterization aspects of the process. The hazard identification and evaluation of dose response are addressed in separate documents.

The exposure assessment is presented in Section a: Occupational and Residential Exposure while the results of the risk assessment and associated risk characterization are presented in Section b: Occupational and Residential Risk Assessment/Characterization.

a. Occupational and Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered <u>and</u> (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. The exposure assessment aspects of the risk assessment have been completed for bensulide and are included in this section of the document.

(1) Summary of Available Products and Use Patterns

Bensulide, S-(0,0-Diisopropyl phosphorodithioate) ester of N-(2-mercaptoethyl) benzenesulfonamide, is a selective

organophosphate herbicide registered for a variety of terrestrial food crop, terrestrial non-food crop, and outdoor residential uses (classifications are based on Agency's Label Use Information System report categories). Bensulide is the only organophosphate pesticide registered for use as a herbicide.

Bensulide is formulated for sale either as an emulsifiable concentrate liquid or as a granular product. There are three emulsifiable concentrate (EC) formulations. Two of the ECs contain 4 pounds of active ingredient per gallon while the remaining formulation contains 6 pounds of active ingredient per gallon. There are several granular formulations that contain bensulide in concentrations of 3.6, 5.25, 7.0, 8.5, or 12.5 percent active ingredient. Liquid emulsifiable concentrate (EC) products are labeled for use in all commercial markets while granular products are labeled for use in only the terrestrial non-food and outdoor residential markets (i.e., granulars are not used in agriculture). The only product labeled for homeowner use is the 3.6G (Reg. No. 869-212). A technical-grade manufacturing product is also available that contains 92 percent active ingredient. Packaging of commercial products appears to be typical with the exception of agricultural uses in the desert southwest and the Rio Grande valley where bulk packaging is apparently a large percentage of the commercial market.

Bensulide is applied as a pre-plant or pre-emergent herbicide in agricultural settings (i.e., to food crops) while non-food/outdoor residential applications (i.e., to turf and ornamentals) are made to established areas such as lawns or golf course greens prior to the emergence of the target plant species. The most likely frequency of application is once per crop per season. In submissions to the Agency, the registrant has indicated that "the herbicidal activity of bensulide is highly dependent on watering the material into the soil soon after application, so it is used almost entirely on irrigated crops and on turf into which it can be watered." Additionally, when applied preplant in agricultural settings, bensulide is generally soil incorporated.

Application rates in agriculture range from a minimum of 3 pounds of active ingredient per acre up to a maximum of 6 pounds of active ingredient per acre on a variety of crops. Bensulide can be applied at a minimum application rate of 7.5

pounds of active ingredient per acre up to a maximum application rate of 12.5 pounds active ingredient per acre to turf and ornamentals. No actual use information was available that could have been used to calculate typical application rates in either agriculture or for other use sites. According to the registrants, "virtually all agricultural uses involve the 4EC formulation" (the 6EC product is relatively new and its overall use is negligible). Additionally, "professional applications on golf course greens and other turf areas ... are generally made with the 4EC formulation, although 12.5%, 8.5%, 7%, and 5.25% granules are also used." The EC formulations account for 85 percent of the bensulide formulated ("both agricultural and turf use") while approximately "8 percent is formulated as granular products for professional use, and approximately 7 percent of the total active ingredient is formulated as a 3.6 percent granule for homeowner use."

As indicated above, bensulide can be applied to terrestrial food crops, terrestrial non-food crops, and in outdoor residential settings. Leafy vegetables, dry bulb vegetables, cucurbits, cole crops, peppers, and carrots account for the majority of the agricultural uses (63.7 percent of all bensulide used). Use on golf greens (terrestrial non-food crops) accounts for another 27.3 percent of the total bensulide used while professionally-treated lawns and lawns treated by homeowners account for approximately another 1.8 and 7.3 percent of all bensulide used, respectively.

Specifically, based on available labeling, bensulide can potentially be used to treat the following crops/targets (examples of each group/type are presented below):

Terrestrial Food Crops Include:

<u>Curcurbit Vegetable Group:</u> Chinese waxgourd, citron melon, cucumbers, gherkin, gourds, cucuzzi, chinese okra, melons (including muskmelon, true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, mango melon, persian melon, pineapple melon, santa claus melon, snake melon), pumpkins, summer squash, winter squash, and watermelons.

<u>Leafy and Stem Vegetable Group:</u> amranth, broccoli, chinese broccoli, raab broccoli, brussel sprouts, cabbage, chinese

cabbage, cardoon, cauliflower, collards, kale, kohlrabi, mustard greens, mustard spinach, rape greens, celery, chinese celery, celtuce, chervil, chrysanthemum, corn salad, cress, dandelion, dock, endive, Florida fennel, lettuce, orach, parsley, radicchio, and swiss chard.

<u>Fruiting Vegetables:</u> Eggplant, ground cherry, pepinos, peppers (bell peppers, chili peppers, cooking peppers, pimentos, sweet peppers), and tomatillo.

<u>Root Crop Vegetables:</u> Carrots, chayote, garlic, onion, and shallots.

Terrestrial Non-Food Crops and Outdoor Residential Targets Include:

<u>Established Turfgrasses:</u> bahiagrass, bentgrass, Bermudagrass, perennial bluegrass, centipede, fescue, pensacola bahia, perennial ryegrass, poa trivialis, St. Augustine grass, red top, and zoysia grass.

<u>Bulbs:</u> daffodil, dahlia, freesia, gladiolus, narcissus, ranunculus, and tulip.

<u>Deciduous Trees, Shrubs, and Evergreens:</u> abelia, azaelea, azara, boxwood, daphne, holly, juniper, monterey cypress, monterey pine, myrtle, privet, pyracantha, sandankwa, tobira, and xylosma.

<u>Ground Covers:</u> ajuga, calendula, hypericum, ice plant, ivy, pachysandra, periwinkle, sedum, and wild strawberry.

<u>Herbaceous Plants:</u> alyssum, aster, bachelor's button, calendula, candy-tuft, coral bell, daisy, marigold, pansy, primrose, stock, sweet pea, and wallflower.

Occupational-Use and Homeowner-Use Products

At this time, products containing bensulide are intended for both occupational and homeowner uses on residential lawns and ornamentals. The 3.6G product (Reg. No. 869-212) is the only product specifically labeled for homeowner use. Several other products (granulars and an EC formulation) can be used

occupationally (by professional applicators) in the residential market.

Modifications Based on Agency Revisions, USDA Comments and/or Gowan Comments

No agency-based modifications are included in this aspect of the assessment. Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998.

Gowan did not dispute the Agency summary of use patterns and use sites provided in this section of the RED document. In fact, Gowan concurred with the maximum application rates identified by the Agency. Additionally, comments were provided that indicate that bensulide is not applied by air, used on sod farms, or in greenhouses. These uses will be restricted by the Agency in the label revision process. Gowan disputed the initial Agency risk assessment for golf course turf by indicating that bensulide is used only on greens and tees. However, no label modification was offered by Gowan "because all products which are actively sold for use on golf courses are registered by other companies" that include PBI/Gordon, The Scotts Company, and United Horticultural Supply and/or its affiliate, the Platte Chemical Company (May 1, 1998 RED Rebuttal letter from Gowan Chemical). Gowan also indicated that such a label restriction would "have little or no impact upon the current use of such [bensulide] products" and that "such a restriction would enable the Agency to reduce its estimates of occupational and nonoccupational exposures from golf courses" (May 1, 1998 RED Rebuttal letter from Gowan Chemical). The Agency added exposure scenarios to address these comments (see below).

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data.

(2) Summary of Toxicology Information

All calculations completed in this document are based on the most current toxicity information available for bensulide, including the recent 21 day dermal toxicity study. The endpoints that were used to complete this assessment are summarized below in order to provide a quick reference or guide to each occupational and residential (handler and postapplication) assessment completed.

	Short-Term Dermal: 50.0 mg/kg/day (based on a 21 day dermal administration toxicity study - 1 assessment completed for both short- and intermediate-term dermal exposures);
<u>.</u>	Intermediate-Term Dermal: 50.0 mg/kg/day (based on a 21 day dermal administration toxicity study - 1 assessment completed for both short- and intermediate-term dermal exposures);
	Absorption Factors: not required for dermal since 21 day dermal administration study used, 100 percent used for inhalation and nondietary oral ingestion;
	Short-term Inhalation: 5.5 mg/kg/day (based on a rat oral administration developmental study);
	Intermediate-term Inhalation: 0.5 mg/kg/day (based on a oral administration 1 year dog feeding study);
	Nondietary (incidental oral) ingestion: 15.0 mg/kg/day (based on an acute rat neurotoxicity study, same as used for acute RfD); and
<u>.</u>	Uncertainty Factors: 100 (10 for intra-species variability, 10 for intra-species variability, and FQPA Safety Factor reduced to 1).

[Note: Any responses to Gowan Company or United States Department of Agriculture comments on the toxicology endpoints are not addressed herein. This section is only intended to serve as a quick reference guide for this document.]

(3) Handler Exposure Scenarios

Exposure scenarios can be thought of as ways of categorizing the kinds of exposures that occur related to the use of a chemical. The use of scenarios as a basis for exposure assessment is very common as described in the *U.S. EPA Guidelines For Exposure Assessment* (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). The purpose of this section is to describe the exposure scenarios that were used by the Agency in the assessment for bensulide handlers and to explain how the scenarios were defined. Information from the current labels; use and usage information; toxicology data; and exposure data were all key components in the developing the exposure scenarios.

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. The agency believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the crop or target being treated, and the circumstances of the user (e.g., the level of protection used by an applicator) can cause exposure levels to differ in a manner specific to each scenario.

The agency uses a concept known as *unit exposure* as the basis for the scenarios used to assess handler exposures to pesticides. *Unit exposures* numerically represent the exposures one would receive related to an application, they are generally presented as (mg active ingredient exposure/pounds of active ingredient handled). The Agency has developed a series of unit exposures that are unique for each scenario typically considered in our assessments (i.e., there are different unit exposures for different types of application equipment; job functions; and levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). The concept of unit exposures can be illustrated by the following example. If an individual makes an application using a groundboom sprayer with either 10 pounds of chemical A or 10

pounds of chemical B using the same application equipment and protective measures, the exposures to chemicals A and B would be similar. The unit exposure in both cases would be 1/10th of the total exposure (measured in milligrams) received during the application of either chemical A or chemical B (i.e., milligrams on the skin after applying 10 pounds of active ingredient divided by 10 pounds of active ingredient applied).

The first step in the handler risk assessment process is to identify the kinds of individuals that are likely to be exposed to bensulide during the application process. In order to do this in a consistent manner, the Agency has developed a series of general descriptions for tasks that are associated with pesticide applications. Common tasks (as an example) can include: preparation of dilute, water-based spray solutions for application; loading solid materials such as granulars into application equipment; transferring or loading dilute spray solutions into sprayers for application; and making applications with specific types of equipment such as a groundboom or airblast sprayer. The Agency also considers whether or not individuals use pesticides as part of their employment (referred to as occupational risk assessments) or if they are individuals who purchase and use pesticide products in and around their residences (referred to as homeowners). Tasks associated with pesticide use (i.e., for "handlers") can generally be categorized using one of the following terms:

- □ Occupational Mixer/loaders: these individuals perform tasks in preparation for an application. For example, they would prepare dilute spray solutions and/or load/transfer solid materials (e.g., granulars) or dilute spray solutions into application equipment such as a groundboom tractor or planter prior to application.
- □ Occupational Applicators: these individuals operate application equipment during the release of a pesticide product into the environment. These individuals can make applications using equipment such as groundboom sprayers or tractor-drawn spreaders for granular materials.
- Occupational Mixer/loader/applicators: these individuals are involved in the entire pesticide application process (i.e., they do all job functions related to a pesticide application

event). These individuals would prepare a dilute spray solution and then also apply the solution. The Agency always considers some exposures to be mixer/loader/applicator exposures because of the equipment used and the logistics associated with such applications. For example, if one uses a small handheld device such as a 1 gallon low pressure handwand sprayer it is anticipated that one individual will mix a spray solution and then apply the solution because of labor and logistical considerations.

Homeowner Mixer/loader/applicators: these individuals are involved in the entire pesticide application process (i.e., they do all job functions related to a pesticide application event). These individuals would prepare a dilute spray solution and then also apply the solution. The Agency always considers some exposures to be mixer/loader/applicator exposures because of the equipment used. For example, if one uses a small handheld device such as a low pressure handwand sprayer then it is anticipated that one individual will mix a spray solution and then apply the solution. This category also encompasses all homeowner applications. The only significant difference between this category and the similar occupational category is that the individuals typically use less chemical on a daily basis and the available levels of personal protection (see below) that are also used to define exposure scenarios are limited and generally less protective.

There are individuals who use bensulide that fit into each of the job function categories described above. Therefore, the bensulide risk assessment for handlers contains exposure scenarios in each category.

The next step in the risk assessment process is to define what kinds of equipment, packaging, and formulation types (as well as other kinds of factors that can vary in specific assessments) can be used by individuals when making bensulide applications. In agriculture, bensulide can be used to treat a variety of vegetable crops including leafy and stem vegetables, cucurbits, and fruiting vegetables. Bensulide labels do not specify particular types of application equipment for these crops as is common for most pesticide labels. Therefore, in order to complete exposure assessments for handlers, the Agency must

evaluate what crops and other targets can be treated and then determine what application methods are likely to be used to make an application to each particular crop or target. It is expected that bensulide applications are routinely made with equipment that is common in agriculture including groundboom sprayers and chemigation (i.e., irrigation) equipment. All applications of bensulide in agriculture involve liquid formulations so no granular applications are anticipated for agricultural crops. Aerial application is also not precluded specifically on any bensulide label, but correspondence from the registrant indicates that all agricultural applications of bensulide, the only scenario for which aerial applications seem appropriate, are completed only using ground equipment. Hence, exposures and risks associated with aerial application are not addressed in this document with the stipulation that the aerial scenario should be addressed during label development to ensure that these use scenarios are not permitted without a risk assessment. The registrant has also indicated that bulk packaging constitutes a large percentage of the bensulide agricultural market, particularly in the desert southwest and the Rio Grande valley.

Bensulide can be applied to established turf and ornamentals using granular formulations or as a dilute spray prepared using a liquid emulsifiable concentrate formulation. Applications can be made by homeowners using only the 3.6G product. A suite of application methods are selected for risk assessment purposes by the Agency when uses on turf and ornamentals are identified because many types of application equipment are available and no application method is specified or precluded on the current labels. Therefore, handlers can use their own discretion to select and use any functional method to make an application. To ensure that the potential risks associated with the use of bensulide are addressed it is necessary to evaluate all potential application methods in the assessment. The suite of application methods selected by the Agency for this risk assessment includes groundboom sprayers that are commonly used on golf courses; handheld sprayers for dilute liquid sprays such as low pressure handwands and specialty turfgun equipment; and equipment for granular applications such as push-type drop spreaders commonly used on lawns. According to the registrant, greenhouse and outdoor uses "in commercial nurseries" are "negligible or nonexistent" even though labelling does not preclude these use patterns. Sod

farm uses are also not included on any label and are actually excluded by EPA Reg. No. 538-26. Hence, exposures and risks associated with greenhouse/nursery and sod farm uses have not been addressed in this document with the stipulation that these scenarios should be addressed during label development to ensure that these use scenarios are not permitted without a risk assessment.

Next, assessors must understand how exposures to bensulide occur (i.e., frequency and duration) and how the patterns of these occurrences can cause the effects of the chemical to differ (referred to as dose response). Wherever possible, use and usage data determine the appropriateness of certain types of risk assessments (e.g., a chronic risk assessment is not warranted for bensulide because chronic duration use patterns do not occur). Other parameters are also defined from use and usage data such as application rates and application frequency. In this case, average application rates were not defined. However, the available labels did indicate both minimum and maximum application rates for many crops and crop groupings. The Agency always completes risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship, in order to ensure the Agency has no concern for the specific use. Additionally, whenever the Agency has additional information such as minimum application rates in this case, it uses the information to further evaluate the overall risks associated with the use of the chemical (i.e., it allows for a more informed risk management decision). The Agency believes that bensulide exposures can occur over a single day or up to weeks at a time even though each crop or established turf and ornamentals are generally treated only once per season. Some applicators may apply bensulide over a period of weeks because they need to cover large acreages, they may be custom or professional applicators that are completing a number of applications within a region, or they may be applying bensulide over a period of several days (e.g., a golf course employee who treats portions of a course over weeks of time). The Agency classifies exposures of one week or less as short-term exposures and exposures of 1 week to several months as intermediate-term exposures. The Agency completes both short- and intermediate-term assessments for occupational users in essentially all cases because acceptable use and usage data are not available to eliminate the intermediate-term scenario. Homeowner applications are always considered short-term in nature. Longterm or chronic exposures (essentially every working day over a year) can also occur for some chemicals. No long-term exposures are associated with the use of bensulide. These classifications are the basis for selecting toxicological endpoints for chemicals in each risk assessment.

A chemical can produce different effects based on how long a person is exposed and the level of exposure that causes an effect can vary with the duration of exposure. Generally, this means that short- and intermediate-term risk assessments are completed for all typical pesticide chemicals. The toxicity of chemicals can also vary based on how a person is exposed. For example, the toxicology database for bensulide indicates that the Agency needs to separately consider exposures to the skin and exposures via inhalation because the effects and the dose levels at which effects occur differ based on whether it gets on skin or it is inhaled. The 21 day dermal toxicity study submitted by the Gowan Chemical Company, selected as a source for the dermal endpoint for bensulide, indicates that effects are similar for both the short- and intermediate-term periods, so all dermal exposures have been considered together in this assessment. Different inhalation toxicity endpoints for each period were selected and, as a result, assessments for both short- and intermediate-term duration inhalation exposure assessments were completed. The toxic effect selected for risk assessment purposes is cholinesterase inhibition. Therefore, the risks resulting from both dermal and inhalation exposures were combined to obtain a total risk for bensulide (see Section 4.b below).

Occupational handler exposure assessments are completed by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario followed by, if required, increasing the levels of risk mitigation (PPE and engineering controls are used for handlers) in order to evaluate if an appropriate margin of exposure can be achieved. This approach is always used by the Agency in order to be able to define label language using a risk-based approach and not solely based on generic requirements for label language. In addition, the minimal level of adequate protection for a chemical is generally considered by the Agency to be the most practical option for risk reduction. For bensulide, four distinct levels of dermal protection were considered in the assessment to account for the use of standard work clothing (long-pants and long-sleeved shirt), standard work clothing with a pair of gloves, standard work clothing with a pair of gloves and an additional layer of clothing

such as coveralls, and the use of engineering controls. Additionally, three levels of respiratory protection were considered in the assessment to account for no respiratory protection, the use of a respirator, and the use of engineering controls. [Note: The manner in which these calculations have been completed allow for flexibility in determining final protective measures -- see Section 4.b for further details.] The levels of protection that formed the basis for the calculations in this assessment include:

- Baseline: Represents typical work clothing or a longsleeved shirt and long pants with no respiratory protection.
 No chemical-resistant gloves are included in this scenario.
- Minimum Personal Protective Equipment (PPE): Represents the baseline scenario with the use of chemical-resistant gloves and a respirator. [Note: This scenario, without a respirator, represents current label requirements for handlers. Risks have been summarized with and without respirators and are discussed in the risk characterization section of the document -- see Section 4.b. below (e.g., the label scenario is addressed in the risk summary aspects of this document).]
- Maximum Personal Protective Equipment (PPE): Represents the baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and respirators.
- ☐ Engineering Controls: Represents the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods there are no known devices that can be used to routinely lower the exposures for these methods.

The premise used by the Agency in homeowner handler assessments is that a tiered mitigation approach is inappropriate because homeowners generally lack access to protective equipment and also lack the appropriate training for proper use. As a result, homeowner handler assessments are completed using a single scenario based on the use of short-sleeved shirts

and short pants (i.e., common homeowner attire during the pesticide application season).

Given all of the information above, the scenarios that have been developed for each specific bensulide market to complete the risk assessment include:

For Occupational Uses on Turf and Ornamentals (*+):

- (1b) mixing/loading liquids for groundboom application;
- (1c) mixing/loading liquids for professional turf applications;
- (2) loading granulars for tractor-drawn spreader application;
- (3) applying sprays with a groundboom sprayer;
- (4) applying granulars with a tractor-drawn spreader;
- (5) mixing/loading/applying with a low pressure handwand;
- (6) mixing/loading/applying with a high pressure handwand;
- (7) mixing/loading/applying with a backpack sprayer;
- (8) mixing/loading/applying with a low pressure/high volume handgun (turf grass application);
- (9) loading/applying with a push-type granular lawn spreader; and
- (10) loading/applying with a bellygrinder.

For Occupational Uses In Agriculture (*+):

- (1a) mixing/loading liquids for chemigation application;
- (1b) mixing/loading liquids for groundboom application; and
- (3) applying sprays with a groundboom sprayer.

For Residential Uses by Homeowners (#+):

- (9) loading/applying with a push-type granular lawn spreader; and
- (10) loading/applying with a bellygrinder.
- * assessed at each appropriate level of personal protection described above
- + assessed at the minimum and maximum application rate # tiered approach for personal protection is not applicable

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

The agency has added exposure scenarios in this section as a result of the comments received from the Gowan Chemical Company in order to address a potential label restriction for use on golf course greens and tees (i.e., an area of 7 acres per day was included for handheld turf equipment on golf course greens and tees -- a value supported by Gowan in the RED rebuttal

comments). Additionally, each of the exposure scenarios included in the original RED handler risk assessment were retained even after comments from the registrant indicated that they are inappropriate (e.g., a groundboom scenario for total golf course treatment is still included as well as new assessments that consider a restriction of bensulide use to golf courses to greens and tees). Another example is the use of high pressure handwands. These devices are still included in the risk assessment because bensulide labels do not specifically preclude them. This results in the selection of a standard suite of handheld equipment when hand applications are allowed by the label (e.g., high pressure handwands, low pressure handwands, backpack sprayers, etc.). The registrant provided anecdotal evidence that these devices are not appropriate. However, no adequate use data were provided to support this claim and thereby justify deleting the devices from the risk assessment.

Several of the comments provided by the Gowan Chemical Company also discussed the appropriateness of completing intermediate-term risk assessments because of the manner in which bensulide is used. It is the policy of the Agency that intermediate-term risk assessments be completed for all agricultural and other occupational use scenarios unless adequate use information were provided to eliminate the scenario from the intermediate-term assessment. The only data provided by Gowan with regard to this comment were anecdotal, thus the scenarios were not removed from the risk assessment.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency attempted to clarify exposure scenarios based on distinct markets for bensulide. Additionally, the Agency also has made a general overall attempt towards more transparency in this risk assessment.

(4) Handler Exposure Assessment

As described in Sections 4.a.2 and 2.a.3 above, the Agency considers how chemical exposures occur including how chemicals enter the body (because the toxic effects can be different) such as absorption through the skin or by being inhaled;

both of these kinds of exposures are typically considered for handlers. Daily dermal exposure levels are calculated in a manner that accounts for the method of application, the level of protection used during application, and the amount of chemical handled in an application (i.e., proportional to application rate and the amount treated per day). Daily dermal exposure levels are then used in the calculation of daily dose levels, and hence the risks for handlers. Daily dermal exposure is generally calculated using the following formula:

DE (mg ai/day) = UE (mg ai/lb ai) x AR (lb ai/A) x A (Acres/day).

Where:

- DE = dermal exposure (amount on the skin) of the active ingredient of a pesticide attributable involvement in the application process;
- UE = unit exposure (derived from PHED) or exposure attributable to using a specific piece of application equipment and protective measures;
- AR = application rate based on the pounds active ingredient applied per acre (or concentration of spray solution as appropriate); and
- A = acres (or volume as appropriate) that can be treated in a workday using the equipment being considered in the assessment (i.e., equipment used for unit exposure and acres per day value must be correlated). [Note: When the high pressure handwand device is used, (lb ai/acre) and (A/day) are replaced, respectively, with (lb ai/gal) and (gal/day).]

Likewise, daily inhalation exposure levels are also calculated in the assessment of risks to handlers. The algorithm used to calculate daily inhalation exposure is essentially the same as that used for the calculation of the daily dermal exposure presented above except that the appropriate unit exposure value for inhalation exposure is used rather than that for dermal exposure. These unit exposure values are based on a human inhalation rate of 29 L/minute and an entire working day.

All handler exposure and risk calculations are presented in the tables contained in *Appendix A: Bensulide Handler Exposure* and *Risk Assessment*. The exposure factors (i.e., descriptions of each scenario, application rates, and acres treated), unit exposure values at varying levels of mitigation (such as personal protection), and toxicological parameters used in the assessment are presented in Appendix A, Table 1. The calculation of baseline exposures (mg/day), dose levels, and the resulting Margins of Exposure (MOEs) for short- and intermediate-term exposures are presented in Appendix A, Table 2 (see section 4.b. for more information concerning calculation of MOEs). Tables 3. 4, and 5 contain similar calculations for increased levels of personal protection. Values calculated for the use of additional mitigation in the form of minimum personal protective equipment are presented in Appendix A, Table 3 while values calculated for the use of additional mitigation in the form of maximum personal protective equipment are presented in Appendix A, Table 4. Table 5 contains values that reflect the use of appropriate engineering controls. Table 6 contains information that can be used to describe the data used in the analysis. For example, the origin of each unit exposure value is presented along with information pertaining to the quality of the data used to calculate each value. The assessment of data quality is based on the number of observations and the available quality control data. The quality control data are assessed based on Agency guidelines and a grading criteria established by the Pesticide Handlers Exposure Database task force. Tables 7 through 10 in Appendix A present summary results of the risk assessment that are discussed in more detail in the section 4.b of this document.

The structure of an exposure/risk assessment as well as the data required to complete the assessment are defined based on how chemicals enter the body and the toxic effects of the chemical once in the body. The Agency has a standing committee of toxicologists (i.e., the HIARC or Hazard Identification Assessment and Review Committee) that review all applicable toxicity data for each chemical and determine the most sensitive effects (toxicity endpoints) and numerical dose values associated with the toxicity endpoints which should be used in the risk assessment. In the two previous versions of the bensulide risk assessment, toxicological endpoints from oral administration studies were selected to address exposures both to the skin (dermal) and from inhalation. The toxicological effect identified in each study (cholinesterase inhibition) was the same as were the uncertainty factors applied to both short- and intermediate-term exposures to account for inter- and intra-species variability (i.e.,

100). The additional safety factor required by the *Food Quality Protection Act* was also reduced to 1. Dermal absorption factors were also applied in each of the previous assessments (i.e., 20 percent reduced to 10 percent in the most recent assessment). The calculations of handler exposures have been modified from the two previous risk assessments because a 21 day dermal toxicity study was submitted to the Agency and selected as a source for the toxicological endpoint for both short- and intermediate-term dermal exposures. In this current assessment, instead of calculating total absorbed dose levels, separate exposures and risks from the dermal and inhalation routes are now calculated individually and then combined to obtain overall risk estimates. The value for the endpoint derived from the 21 day dermal study is 50 mg/kg/day which is the NOAEL (No Observed Adverse Effect Level) in the study.

The factors described in the exposure calculation above are discussed below. These factors include: unit exposures; application rate; and acres treated per day.

Chemical-specific exposure data for pesticide handling activities were not submitted to the Agency in support of the (re)registration of bensulide. It is the policy of the Agency to use data from the *Pesticide Handlers Exposure Database (PHED) Version 1.1* to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts --a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored application events (i.e., referred to as replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body. The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. It should also be noted that distributional analyses of the data contained in PHED are not done for the risk assessment process because the available data do not lend themselves to this kind of analysis.

To add consistency to the values produced from this system and to ensure quality control, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table 6. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. The Agency has developed a series of tables of standard unit exposure values (i.e., representing the "best fit" for each dataset) for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.

In addition to PHED, the application rate and daily amount treated (usually acres per day) are also key elements in the

calculation of handler exposures. A range of application rates, derived from bensulide labelling, serves as the basis for this assessment. The Gowan Chemical Company, the registrant, concurred with the maximum application rates used by the Agency in its RED Rebuttal letter of May 1, 1998. The range of application rates in this assessment is defined by the minimum and maximum application rate values specified on the bensulide labels (see Section 4.a.1). Application rates specified on bensulide labels range from 3 to 6 pounds of active ingredient per acre in agricultural settings and from 7.5 to 12.5 pounds of active ingredient per acre on turf and ornamentals. Insufficient information was available to determine typical application rates. However, this lack of data has little impact on the risk assessment because there is only about a factor of 2 difference in the range of application rates, based on the labels, already used in the risk assessment.

The amount treated per day, usually expressed as the number of acres treated per day, is the other factor that is critical in the exposure calculations for handlers. The Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for specific types of application equipment. The Agency has used the same default values for acres treated per day for several years. These values were based on data included in PHED, consideration of agricultural engineering principles, and use and usage information. Through NAFTA (North American Free Trade Agreement) auspices, there is currently an initiative underway to harmonize the acres treated per day values used for the purposes of risk assessment. The values currently used by the Agency are similar or equivalent to those being discussed in the NAFTA working group. It should also be noted that the only acres treated per day values, in previous assessments, commented upon by the registrant were for chemigation and on golf courses. For chemigation, the Agency included an assessment for the standard value of 350 acres per day treated as well as a registrant supplied value of 40 acres per day in order to provide more information for risk managers. For golf courses, the issue was focused on the amount of area that can be treated on a golf course and label use restrictions to greens and tees. In the original assessment, the Agency used a value of 40 acres because there are no label restrictions precluding the use of bensulide over an entire course. The registrant commented that only about 7 acres are treated on

an average golf course or those areas covered by greens and tees and that bensulide is generally only used to treat the greens and tees. The Agency also included this information in order to provide more information to risk managers. The issues presented here related to the numbers of acres treated per day are also generically addressed in the science issue paper on use and usage that was presented to the Agency's Tolerance Reassessment Advisory Committee (TRAC) for consideration in 1998. The actual values, specific to each scenario in the risk assessment, are presented below.

In addition to the information presented above, the following assumptions and factors were used in order to complete this exposure assessment:

- Exposure data that can be used to address the use of bulk packaging are not available nor have any chemical-specific bulk packaging data been submitted by the registrant. Therefore, bulk packaging exposures are addressed using the best available exposure data (i.e., data generated using more typical packaging).
- An average work day interval represents an 8 hours per workday. The definition of a workday has been used by the Agency to define the number of acres that could be treated based on the application method and application site. The values used by the Agency to represent the amount of acres that can be treated in a day (or application volumes as appropriate) for each scenario include:

For Occupational Uses on Turf and Ornamentals:

- (1b) 40 acres (an entire golf course) for mixing/loading liquids for groundboom application;
- (1c) 50 acres (10 trucks/day x 5 acres/truck) for mixing/loading liquids for professional turf applications;
- (2) 40 acres (an entire golf course) for loading granulars for tractor-drawn spreader application;
- (3) 40 acres (an entire golf course) for applying sprays with a groundboom sprayer;
- (4) 40 acres (an entire golf course) applying granulars with a tractor-drawn spreader;
- (5) 7* acres of greens and tees or 5 acres of residential lawns for mixing/loading/applying with a low pressure handwand:
- (6) 1000 gallons for golf courses (greens and tees) and residential lawns for mixing/loading/applying with a high pressure handwand:
- (7) 7* acres of greens and tees or 5 acres of residential lawns for mixing/loading/applying with a backpack sprayer;
- (8) 7* acres of greens and tees 5 acres of residential lawns for mixing/loading/applying with a low pressure/high volume turf handgun;
- (9) 5 acres of residential lawns for loading/applying with a push-type granular lawn spreader; and

(10) 5 acres of residential lawns for loading/applying with a bellygrinder.

For Occupational Uses In Agriculture:

- (1a) 40 and 350* acres for mixing/loading liquids for chemigation application;
- (1b) 80 acres for mixing/loading liquids for groundboom application; and
- (3) 80 acres for applying sprays with a groundboom sprayer.

For Residential Uses by Homeowners:

- (9) 0.5 acres for loading/applying with a push-type granular lawn spreader; and
- (10) 0.5 acres for loading/applying with a bellygrinder.
- * = added based on registrant comments
- The values for groundboom applications in agriculture and on turf/ornamentals vary. Groundboom applications in an agricultural setting are based on an 80 acre day because the Agency believes it would take 8 hours to complete that type of application with common equipment and that acreage estimate for various crops is reasonable. On the other hand, the value for groundboom applications on golfcourse turf is based on treating 40 acres because that is the value calculated to represent a 36 hole course (they account for about 10 percent of all golf courses based on previous registrant comments and investigation by Agency personnel). The 40 acre value is not the maximum that can be treated on a single day given that the application equipment is likely capable of treating higher acreages. The daily limitation of 40 acres per day is based on the fact that an applicator would only treat a course a single time on any given day.
- As indicated above, the Agency has developed a series of unit exposures that can be used in risk assessments for different application equipment and varying levels of protection. Due to a lack of empirical, scenario-specific data, unit exposures are sometimes calculated using generic protection factors that are intended to represent the protectiveness of various risk mitigation options (i.e., the use of PPE or Personal Protective Equipment and engineering controls). PPE protection factors include those representing layers of clothing (50%), chemical-resistant gloves (90%), and respiratory protection (80 to 95% depending upon

mitigation selected). Engineering controls are generally assigned a protection factor of 98 percent. Engineering controls may include closed mixing/loading systems, closed cabs/cockpits, and "Lock-n-Load" type systems for granulars. Adjustments to exposure values using protection factors are made using the following equation and are completed only in lieu of scenario-specific monitoring data (PF = Protection Factor expressed as a percent reduction):

PF Adjusted Exposure = (1-(PF/100)) * (Nonadjusted Exposure Value)

Baseline occupational assessments and homeowner applicator unit exposures are typically calculated based on empirical data that is reflective of the scenario. In other words, the empirical data in PHED used to generate exposure values are generally monitoring data that were generated in which the individuals tested were wearing clothing similar to the occupational baseline (long pants and long-sleeved shirt) and the homeowner applicator (short pants and short-sleeved shirts).

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

Scenarios were added to the risk assessment based on the discussion provided in the previous section with respect to the selection of exposure factors and understanding of the use patterns. Several modifications have been made in this aspect due to modifications in the hazard aspects of the risk assessment. No other agency-based modifications are included in this aspect of the assessment.

Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998. Several of the comments provided by the Gowan Chemical Company discussed the appropriateness of completing intermediate-term risk assessments because of the manner in which bensulide is used. It is Agency policy that intermediate-term risk assessments be completed for all agricultural and other occupational use scenarios unless adequate use information were provided to eliminate the scenario from the intermediate-term assessment. The only data provided by Gowan with regard to this comment

were anecdotal, thus the scenarios were not removed from the risk assessment.

The agency has also revised certain unit exposure values in order to reflect the latest analysis of PHED data. These modifications reflect minor changes in Agency policy regarding use of certain data in the system. One error in the unit exposure values was also corrected.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency has attempted to address all comments and to make a general overall attempt towards more transparency in this risk assessment.

(5) Post-Application Exposure Scenarios

Bensulide can be used in agriculture; for professional turf management purposes (e.g., on golf courses) and in the residential environment. As a result, individuals can be exposed to chemicals by entering previously treated areas and engaging in activities that could contribute to exposure. The Agency is concerned about exposures one could receive in the workplace or in other areas the are frequented by the general population, including residences. The purpose of this section of the document is to explain how exposure scenarios were developed for each setting where bensulide can be used. Exposure scenarios can be thought of as ways of categorizing the kinds of exposures that occur related to the use of a chemical. The use of scenarios as a basis for exposure assessment is very common as described in the U.S. EPA Guidelines For Exposure Assessment (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992).

The Agency uses the term "post-application" to describe those individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain job tasks or activities (also often referred to as reentry exposure). As with the handler risk assessment scenarios described above in Section 4.a.3, the agency believes that there are distinct job tasks

and also non-work related activities (e.g., children playing on a treated lawn) that occur in areas previously treated with bensulide that may contribute to exposure. The Agency also believes that the resulting exposures can vary depending upon the specifics of each task or activity and the levels of chemical residue available in the environment. The nature of the treated area (e.g., crop foliage level) and the duration of activity of the individual can also cause exposure levels to differ in a manner specific to each setting considered.

The agency uses a concept known as the *transfer coefficient* to numerically represent the post-application exposures one would receive (i.e., generally presented as cm²/hour). The transfer coefficient concept has been established in the scientific literature and through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). Transfer coefficients are also the basis of the Agricultural Reentry Task Force, of which, the Gowan Chemical Company is a member. The transfer coefficient is essentially a measure of the contact with a treated surface one would have while doing a task or activity. These values are defined by calculating the ratio of an exposure for a given task or activity to the amount of pesticide on leaves (or other surfaces) that can rub off on the skin resulting in an exposure. For postapplication exposures, the amounts that can rub off on the skin are measured using techniques that specifically determine the amount of residues on treated leaves or other surfaces (referred to as transferable residues) rather than the total residues contained both on the surface and absorbed into treated leaves. Transfer coefficients can be illustrated by the following example. Consider two vegetable fields where the amount of chemical on treated leaf surfaces that can rub off on the skin is the same. One field has been treated with chemical A while the other field has been treated in a similar manner with chemical B. If an individual harvests vegetables for a day in each field, the exposures the individual would receive would be similar. The transfer coefficient would also be similar for each field and chemical because the ratio of exposure to residue would be the same. If the same individual would do another activity in those fields such as scout the vegetables for pests or tie the vegetables, the exposures would be different as would the resulting transfer coefficients because the activity that resulted in

the exposures is different. In this example, three distinct transfer coefficients could be determined for vegetable crops: harvesting; scouting; and tying. The Agency has developed a series of standard *transfer coefficients* that are unique for variety of job tasks or activities that are used in lieu of chemical- and scenariospecific data.

Like with the handler risk assessment process, the first step in the post-application risk assessment process is to identify the kinds of individuals that are likely to be exposed to bensulide after application. In order to do this in a consistent manner, the Agency has developed a series of general descriptions for tasks that are associated with post-application exposures. The Agency also considers whether or not individuals are exposed to pesticides as part of their employment (referred to as occupational risk assessments) or if they are individuals who are exposed to pesticide products in and around their residences or other areas frequented by the general public. Tasks associated with post-application exposures can generally be categorized using one of the following terms:

- □ Post-application workers: these individuals perform tasks as part of their employment that cause them to enter areas previously treated with a pesticide and complete these tasks. Common examples include: agricultural harvesters, individuals involved in turf management, and scouting activities in agriculture.
- □ Residential Adults: these individuals are members of the general population that are exposed to chemicals by engaging in activities in areas not limited to their residence (e.g., golf courses) previously treated with a pesticide. These kinds of exposures are attributable to a variety of activities and usually addressed by the Agency in risk assessments by considering a representative activity that results in a conservative exposure calculation.
- □ Residential Children: these children (i.e., toddlers have been selected as a sentinel exposure population) are members of the general population that are exposed to chemicals by engaging in activities in areas not limited to their residence (e.g., parks) previously treated with a pesticide. These kinds of exposures are attributable to a variety of activities (e.g., playing outside on the lawn), and usually addressed by the Agency in risk assessments by considering a representative activity that results in a conservative exposure calculation.

There are individuals who are potentially exposed to bensulide that fit into each of the categories described above. Therefore, the bensulide post-application exposure/risk assessment contains exposure scenarios in each category.

The next step in the risk assessment process is to define how and when chemicals are applied in order to determine the level of transferable residues to which individuals could be exposed over time (i.e., to aid in the design of studies and to refine the risk assessment). Wherever available, use and usage data are used in this process to define values such as application rates and application frequency. The Agency always completes risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship in order to ensure the Agency has no concern for the specific use. Additionally, whenever the Agency has additional information, such as minimum application rates or application frequency, it uses the information to further evaluate the overall risks associated with the use of the chemical (e.g., only a single application was considered for the bensulide postapplication risk assessment). In order to define the amount of transferable residues to which individuals can be exposed, the Agency relies on chemical- and crop-specific studies as described in the Agency guidelines for exposure data collection (Series 875, Occupational and Residential Exposure Test Guidelines: Group B - Postapplication Exposure Monitoring Test Guidelines). The Agency developed a standard modeling approach that can also be used to predict transferable residues over time in lieu of chemical- and scenario-specific data. In the previous two bensulide risk assessments, the standard modeling approach was used. In this version of the risk assessment a more refined approach is used because data from a chemicalspecific study were submitted and used in the risk calculations.

Defining the activities that could lead to exposures related to the use of the chemical is also a critical aspect of the process. Generally, this can be a difficult aspect of the risk assessment process in that many activities are plausible and dynamics of the population of interest constantly change. As such, the Agency currently uses scenarios that represent activities related to the populations of concern. Bensulide labels allow for uses on turf and in agriculture. Bensulide can also be used in a residential environment meaning that both children and adults can potentially be exposed. Bensulide is used as a pre-plant, pre-emergent herbicide in agriculture. Therefore, the Agency is not concerned about post-application exposures with the agricultural uses given additional confirmatory information. As a result of turf chemical

uses, however, the Agency does have concerns for exposures to both adults and children. The Agency considered both low exposure (e.g., golfing and light yard work) and high exposure (e.g., heavy yard work) activities for adults. In order to adequately consider the risks to children, the guidance from the Agency's SOPs For Residential Exposure Assessment was used to address the exposures of children on recently treated turf. The SOPs use a high contact activity based on the use of Jazzercise to represent the exposures of an actively playing child.

Next, assessors must understand how exposures to bensulide occur (i.e., frequency and duration) and how the patterns of these occurrences can alter the effects of the chemical in the population after being exposed (referred to as dose response). The Agency believes that bensulide exposures can occur over a single day or up to weeks at a time even though established turf and ornamentals are generally treated only once per season. This is supported by the length of time that residues took to decline in the bensulide turf transferable residue study submitted by the Gowan Chemical Corporation for use in this risk assessment and the fact that several areas within a work environment may be treated at different times. For example, a golf course might be treated over several weeks (e.g., a hole or two per week). Therefore, individuals working on the course might be exposed from contact with treated turf over an extended period of time that could be categorized as an intermediate-term exposure as they work on different sections of the course. Typically, the Agency conducts separate assessments for exposures that are one week or less, and also for periods greater than one week up to several months. The Agency classifies these as short-term exposures (one-week or less) and intermediate-term exposures (seven days to several months), respectively. Long-term or chronic exposures (essentially every working day over a year) can also occur for some chemicals. However, no long-term exposures are associated with the use of bensulide. These classifications are the basis for selecting toxicological endpoints for chemicals and are generally included in each risk assessment. A chemical can have different effects based on how long or how often a person is exposed. The toxicity of chemicals can also vary based on how a person is exposed. The toxicology database for bensulide indicates that the Agency needs to separately consider exposures to the skin and exposures via inhalation because the effects and the dose

levels at which effects occur differ based on whether it gets on skin or it is inhaled. A dermal toxicity study (selected as a source for the dermal endpoint for bensulide) indicates that effects are similar for both the short- and intermediate-term periods, so all dermal exposures have been considered together in this assessment. Inhalation exposures are thought to be negligible in outdoor post-application scenarios because of the low vapor pressure of bensulide and because the uses (and primary exposures) are outdoors allowing for significant dilution. Empirical data have also shown inhalation exposures, in outdoor settings analogous to those considered in this risk assessment, to be negligible. As such, inhalation exposures are not considered in this assessment.

The use of personal protective equipment or other types of equipment to reduce exposures for post-application workers is not considered a viable alternative for the regulatory process except in specialized situations (e.g., a rice scout will wear rubber boots in flooded paddies). As such, an administrative approach is used by the Agency to reduce the risks and is referred to as the Restricted Entry Interval or REI. The REI is a measure of the time it takes for residue levels to decline to a point that entry into a previously treated area and engaging in a task or activity would not result in exposures that exceed the Agency's level of concern. REIs are generally established in the risk assessment process on a chemical-, crop-, and activity-specific basis. REIs are not considered a viable regulatory tool for reducing exposures and risks in the residential environment (i.e., for the general population). Therefore, for chemicals used in the residential environment or any other areas where the general population can be exposed, regulatory risk management currently considers the risks associated with a chemical on the day it is applied.

Given all of the above information, four scenarios have been developed for exposures related to turf uses as the basis for this risk assessment (the adult scenarios are used in both the occupational and residential settings). Exposures in the agricultural settings were also considered but an assessment was not completed for them (see further explanation below). The scenarios considered in this assessment are presented below:

For Occupational Uses on Turf and Ornamentals (*+):

(i) adults involved in a low exposure activity, such as moving cups on golf course greens, at the lowest prescribed application rate for turf (i.e., dose levels are equal to residential adult scenario 1); and

(ii) adults involved in a high exposure activity, such as heavy weeding or other turf management activity, at the highest application rate for turf (i.e., dose levels are equal to residential adult scenario 2).

For Occupational Uses In Agriculture:

In agricultural settings, bensulide is applied as a pre-plant or preemergent herbicide. According to comments from Gowan Chemical Company, "the herbicidal activity of bensulide is highly dependent on watering the material into the soil soon after application, so it is used almost entirely on irrigated crops and on turf into which it can be watered." Additionally, when applied preplant in agricultural settings, bensulide is soil incorporated. Likewise, high exposure activities associated with the use of bensulide are not anticipated because the activities related to the cultivation of the target agricultural crops, early in the season when bensulide is typically applied, are limited and typically do not require intense contact with treated areas. As a result, no assessment was completed for any agricultural use scenario as bensulide is a pre-plant/pre-emergent herbicide. However, additional data on cultural practices are needed for the Agency to completely address concerns over the involvement of individuals in mechanically assisted transplanting operations that are possible with the various vegetable crops on which bensulide can be used. In these operations, personnel can potentially be exposed because they come into contact with the surfaces of the transplanting equipment during operation and it is possible that residues can accumulate on these surfaces.

For Residential Uses (#+):

- (i) adults involved in a low exposure activity, such as golfing, at the lowest prescribed application rate for turf (i.e., dose levels are equal to occupational adult scenario 1);
- (ii) adults involved in a high exposure activity, such as heavy yardwork, at the highest application rate for turf (i.e., dose levels are equal to occupational adult scenario 2);
- (iii) toddlers involved in a high exposure activity at the lowest prescribed application rate for turf (i.e., dermal and nondietary ingestion calculations included); and

- (iv) toddlers involved in a high exposure activity at the highest prescribed application rate for turf (i.e., dermal and nondietary ingestion calculations included).
- * assessed to determine Restricted Entry Interval
 + assessed at the minimum and maximum application rate
 # administrative controls for risk mitigation, such as Restricted

Entry Intervals, are not applicable

[Note: The dose levels calculated for adults were used for establishing restricted entry intervals for adults engaged in activities related to occupational turf management and for use in the residential aggregate risk assessment. Toddler levels were calculated solely for the residential exposure assessment and for the purposes of completing an aggregate risk assessment that also considers exposure from dietary intake of food and water.]

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

No agency-based modifications are included in this aspect of the assessment except for the fact that the 21 day dermal toxicity study serves as the basis for the risk assessment and that the nondietary ingestion pathways have been added to address toddler exposures. Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998.

Several of the comments provided by the Gowan Chemical Company in their RED rebuttal discussed the appropriateness of completing intermediate-term risk assessments on turf. The turf transferable residue dissipation and 21 day dermal toxicity studies submitted by the Gowan Chemical Company alleviated these comments.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency has attempted to address all comments and to make a general overall attempt towards more transparency in this risk assessment.

(6) Post-Application Exposure Assessment

As described in Sections 2.a.2 and 2.a.5 above, the Agency considers how chemical exposures occur including how chemicals enter the body (because the toxic effects can be different) such as absorption through the skin or by being inhaled, both of these kinds of exposures are typically considered for handlers. The calculations completed to address post-application exposures are presented below. In the previous two assessments for bensulide, the Agency used a generic modeling approach to determine post-application turf transferable residue levels because no chemical-specific data were available. The values generated with this approach were coupled with the standard Agency approaches for calculating dermal exposures. Dermal exposures were the only exposures that were addressed in the previous assessments because the Agency had concerns over exposures from just that single route of exposure. In response to the previous two exposure/risk assessments for bensulide, the Gowan Chemical Company generated a turf transferable residue study for bensulide (MRID 447990-01) in order to refine the previous risk assessments for turf uses. The Agency used these data to assess both exposures to the skin (i.e., dermal) and exposures involving the mouthing activity of children (i.e., nondietary ingestion).

In order to clearly present the current post-application exposure assessment, it is necessary to present the data upon which it is based. The study used to determine the turf transferable residue levels for risk assessment purposes can be identified by the following information:

Title:	Determination of Transferable and Total Turf Residues on Turf Treated With Bensulide				
Author:	Erik R. Gouker, ABC Laboratories, California				
Study Director:	Thomas C. Mester, Ph.D. ABC Laboratories California 32380 Avenue 10 Madera California 93638				
Analytical Laboratory	ABC Laboratories, Inc. 7200 E. ABC Lane Columbia, Missouri 65202				
Study Identification Codes:	ABC/CA Study No.: 98703 ABC/MO Study No.: 44679 EPA MRID No.: 447990-01				
Report Date	March 16, 1999 (Amended April 6, 1999)				

A review of this study indicates that it is acceptable for the purposes of this risk assessment. This study was conducted in Wayne County, New York, which is approximately 50 miles west of Syracuse. The field sampling aspects of the study were completed between June 2, 1998 (application day) and July 7, 1998. A typical formulation of bensulide, Bensumec 4LF (a 4 pound active ingredient per gallon liquid), was used to treat the turf (i.e., Kentucky Bluegrass) at an application rate of 12.6 pounds of active ingredient per acre. The application was made using a typical groundboom sprayer in a dilute solution that would be equivalent to applying the bensulide in 100 gallons of water per acre. The treated plot had an area of 4,275 ft² with dimensions of 45 feet by 95 feet. A separate control plot was also established. The treated plot was mowed four times throughout the study, particularly on June 10th, 16th, and 23rd and on July 2nd. Since bensulide is a herbicide that requires watering-in to be efficacious according to the Gowan Chemical Company (and it is a label requirement). On the day of application, 0.56 inches of irrigation water were applied to the treated site. In addition to the irrigation event, rainfall was monitored at the site on 18 days throughout the study. Daily rainfall amounts ranged from a trace to 1.42 inches. The total amount of rainfall received throughout the course of the study was 8.12 inches, which when combined with the irrigation water is equivalent to a total of 8.68 inches of water on the treated site (in many cases, this amount of rainfall

would diminish the utility of the data included in this kind of study; the data are acceptable, however for the purposes of this risk assessment).

The Gowan Chemical Company is a member of the Outdoor Residential Task Force that was formed to respond to the requirements of the 1995 Data Call-In issued by the Agency for turf exposure data. The objective of this task force is to provide information concerning handler exposures, post-application dermal exposures, and guidance for conducting the chemicaland scenario-specific data necessary for use with the postapplication dermal exposure data in exposure/risk assessments. This study was conducted according to the protocol developed by the ORETF and accepted by the Agency, Health Canada, and the California Department of Pesticide Regulation for gathering TTR (Turf Transferable Residue) data. TTR represents the amount of the applied chemical that is available on treated surfaces that can rub off onto skin as a result of contact with those treated surfaces. TTR samples were collected using a modified California roller technique (a weighted roller traversed 5 times over a frame with a total sample collection surface area of 5690 cm² placed on turf with a cotton sheet used as the sample media) as described in the generic protocol. Samples from both the treated and control plots were collected at the following intervals: on the day of application (pre- and post-application, and between 8 and 12 hours after application and an irrigation event); plus 1, 2, 3, 4, 5, 6, 7, 10, 14, 21, 28, and 35 days after application. Triplicate TTR samples were collected from the treated plot while single control samples were collected at each interval.

In addition to the TTR sampling component of this study, duplicate grass clipping samples were collected at each sampling interval. These samples were macerated and analyzed for total residue levels (i.e., this approach measures the chemical on the surface of the plants and that which is absorbed into the plant). "Grass leaves were collected ... by placing a one-square foot frame in the subplot and then clipping the grass with battery powered grass shears just above the plant crown" and the weight of each sample was recorded.

All samples were handled using normal sample handling procedures (i.e., on blue ice in the field and then into the freezer). Samples were shipped in a freezer truck and maintained in

freezer storage at -20°C. The analytical methods used for quantifying both the TTR and the total residue samples used a gas chromatograph and extraction with a methanol/water solution (TTR) or toluene (total grass residues). All samples were analyzed for both bensulide and bensulide oxon residues. Sensitivity of the methods for both TTR and total residues are summarized below in table 9:

Table 9. Sensitivity of the Analytical Methods

Value	Bensulide		Bensulide Oxon		
	TTR (μg/cm²)	Total Residues (ppm)	TTR (μg/cm²)	Total Residues (ppm)	
LOQ	0.0014	0.05	0.0014	0.05	
LOD	0.00088	0.03	0.00088	0.03	

LOQ = Limit of Quantification & LOD = Limit of detection

Several types analytical quality control data were generated in this study. These data included laboratory recoveries, field recoveries for the TTR samples, and method validation data for all media. The field recovery samples were analyzed in a manner that reflected the storage interval for the field samples. Field recovery samples were generated on two days of the study. The quality control data from the study are summarized in table 10 below:

Table 10. Quality Control Data

Table 10. Quality Control Data									
Sample Type	Bensulide Results			Bensulide Oxon Results					
	Range (% recovery)	Mean ± S.D.* (% recovery)	C.V.*	Range (% recovery)	Mean ± S.D.* (% recovery)	C.V.*			
For TTR Sample Method									
Method Validation	71 to 98	86 & 90	6.0 & 9.7	79 to 108	96 & 101	5.0 & 8.9			
Laboratory Recovery	56 to 96	82 ± 15	18.3	61 to 112	94 ± 16	17.0			
Field Recovery	73 to 121	94 ± 14	14.9	68 to 128	94 ± 19	20.2			
For Total Residue Samples #									
Method Validation	98 to 106	101 ± 2.8	2.8	88 to 100	95 ± 4.1	4.3			
Laboratory Recovery	72 to 122	99 ± 12	12.1	72 to 115	92 ± 13	14.1			

^{* =} Data for different fortification levels are reported. Data for lowest level are reported first on the left. C.V. = coefficient of variation.

^{# =} Field recovery data for total residue samples were not completed in this study. Instead, the authors referenced a variety of residue storage stability studies in agricultural commodities.

All residue data generated in this study are presented in the Appendices of this document. Specifically, the TTR data are included in Appendix B/Table 1 and also in Appendix C/Table 1. The total residue data are presented in Appendix C/Table 4. The data were not corrected for recovery for use in this risk assessment because the average field recovery data for bensulide and bensulide oxon in the TTR samples exceeded 90 percent and the average recovery in a types of samples exceeded 90 percent for the total residue samples. The data from the studies were used in the exposure assessment by the Agency after it had been evaluated using standard kinetics approaches and also using the directly measured values. The standard approach for analyzing the dissipation kinetics of transferable residues is described in the Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version). This approach involves a semilog regression of the data (i.e., calculating an equation for a line based on a plot of the natural log of the concentration versus the sampling time) and the use of pseudo-first order kinetics model based on the equation:

$$C_t = C_0 e^{-(m^*t)}$$

where:

 C_t = concentration of TTRs or Total residues at time (t), presented as (μ g/cm2 for TTRs or ppm for total residues);

 C_0 = concentration of TTRs or Total residues at time (0), presented as (μ g/cm2 for TTRs or ppm for total residues);

e = inverse of the natural log function;

m = slope of the line calculated for the data (natural log versus time); and

t = time interval of interest (days).

[Note: All exposure and dose calculations completed in this assessment have also been completed using actual measured values because of the dissipation pattern exhibited in the data.]

The structure of an exposure/risk assessment as well as the data required to complete the assessment are defined based on how chemicals enter the body and the toxic effects of the

chemical once in the body. The Agency has a standing committee of toxicologists (i.e., the HIARC or Hazard Identification Assessment and Review Committee) that review all applicable toxicity data for each chemical and determine what effects should be considered in the risk assessment as well as the numerical dose values associated with the toxicity endpoints to be used in the risk assessment. In the two previous versions of the bensulide risk assessment, toxicological endpoints from oral administration studies were selected to address exposures to the skin (dermal). [Inhalation exposures are not addressed as described in Section 4.a.5 above.] The toxicological effect identified in each study (cholinesterase inhibition) was the same as were the uncertainty factors applied to both short- and intermediate-term exposures to account for inter- and intraspecies variability (i.e., 100). The additional safety factor required by the Food Quality Protection Act was also reduced to 1. Dermal absorption factors were also applied in each of the previous assessments (i.e., 20 percent reduced to 10 percent in the most recent assessment). The calculations of handler exposures have been modified from the two previous risk assessments because a 21 day dermal toxicity study was submitted to the Agency and selected as a source for the toxicological endpoint for both short- and intermediate-term dermal exposures. The value for the endpoint derived from the 21 day dermal study is 50 mg/kg/day which is the NOAEL (No Observed Adverse Effect Level) in the study. Additionally, this assessment considers children's exposures that occur from nondietary ingestion. The endpoint used for that assessment is the same one used to calculate the acute reference dose in dietary risk assessment (15 mg/kg/day).

Doses attributable to various exposure routes and pathways must be aggregated according to the *Food Quality Protection Act* for calculating risks in the residential environment. In the previous assessments, exposures to the skin (dermal) alone were enough for the Agency to have a level of concern over the use of bensulide on turf. Therefore, in the previous assessments, dose aggregation (i.e., adding together of exposures from various sources) was not completed by the Agency. In the current assessment, the nature of the data from the study and the calculated risks lend themselves to considering exposures from more than one source (i.e., to aggregate or add doses together from various sources). The data from this study were coupled

with the same dermal transfer coefficients, exposure duration values, and other exposure factors used previously to add refinements to the current bensulide assessment. In addition to the dermal exposure calculations included previously, other routes/pathways of exposure were considered in this current assessment (i.e., hand to mouth activity on treated turf). Specifically, the Agency calculated dose levels attributable to exposures on the skin; exposures from mouthing treated grass; and exposures from hand-to-mouth contacts with treated turf. All calculations but the ingestion of treated turf are based on the current version of the Agency's SOPs For Residential Exposure Assessment. The Agency's approach for each exposure calculation is presented below. The risk calculations are described in Section 4.b. of this document.

Dermal Exposure values on each post-application day after application were calculated based on the following equation (see **SOP 2.3.1:** Postapplication dermal potential dose from pesticide residues on turf):

 $DE_{(t)}$ (mg/day) = (TTR_(t) (μ g/cm²) x TC (cm²/hr) x Hr/Day)/1000 (μ g/mg)

Where:

DE = Dermal exposure at time (t) attributable for activity in a previously treated area (mg/day);

TTR = Turf Transferable Residue at time (t) where the longest duration (t) is dictated by the kinetics observed in the TTR study;

TC = Transfer Coefficient; and Hr = Exposure duration in hours.

As indicated above, the transferable residue represents the amount of chemical on the surfaces of treated leaves that can rub off on one's skin. The transfer coefficient is a value that represents the exposure one receives while performing a specific task or activity in an area previously treated with a pesticide. Exposure duration values represent the amount of time that individuals are expected to spend engaged in a job task or activity.

In addition to the TTR data from the study, transfer coefficients and duration of exposure are also key elements in the calculation of post-application exposures. A range of application rates, derived from bensulide labelling, was used as the basis for this assessment (i.e., a ratio of rates is used to adjust the TTR data from the study). The activities that were selected as the basis for the risk assessment (these have not been altered since the previous assessment) are represented by the following transfer coefficients:

- (i) Transfer Coefficient = 1000 cm²/hour for adults involved in a low exposure activity on turf such as golfing or light work activities;
- (ii) Transfer Coefficient = 10000 cm²/hour for adults involved in a high exposure activity on turf such as heavy yardwork or golf course maintenance; and
- (iii) Transfer Coefficient = 8700 cm²/hour for toddlers involved in a high exposure activity. This value is stipulated in the Agency's SOPs For Residential Exposure Assessment (SOP 2.3.1: Postapplication dermal potential dose from pesticide residues on turf).

[Bensulide use patterns were also evaluated in the agricultural marketplace and determined that the potential for post-application agricultural worker exposure is minimal due to the timing of applications and given the mode of action as a herbicide (i.e., it is watered in and sometimes soil incorporated). Additional data are needed by the Agency to completely address this exposure scenario as described above. Additionally, there are no apparent sod farm uses so this occupational exposure scenario was not considered in this assessment.]

The typical occupational work day interval is generally considered to be 8 hours. However, since the primary concern for post-application bensulide exposure is non-agricultural occupational, and non-occupational exposure to treated turf (e.g., golf courses and residential), the duration of exposure values used in the assessment for adults is 4 hours of activity on a single day. This is a reasonable estimation of the duration one might be outside and engaged in the activities considered in this risk assessment. Additionally, the 4 hour value was selected so that

the dose levels calculated for adults could be used in both the occupational and homeowner exposure assessments. The 2 hour duration of exposure used for the toddler risk assessment is referenced directly from the SOPs For Residential Exposure Assessment and is also a recommended value from the U.S. EPA Exposure Factors Handbook (U.S. EPA, 1997).

The results of the dermal exposure calculations are presented in Appendices B and C. The calculations that have been completed for adults (same doses and MOEs used for occupational and residential assessments) are presented in Appendix B. Table 1 contains the kinetics analysis of the TTR data contained in the study (completed using a commercial spreadsheet program). Table 2 contains the exposures, doses, and MOEs attributable to bensulide exposure for adults completing activities on turf at the lowest and highest allowable application rates (i.e., lowest rate values were calculated using a simple proportion and the study data which were developed at the highest application rate). Exposures for both heavy and light activities are also considered in this table. Table 3 is essentially the same as Table 2 except that both bensulide and bensulide oxon residues are considered in the assessment. The calculations that have been completed for children (using toddlers as the sentinel population) are presented in Appendix C. Table 1 contains the kinetics analysis of the TTR data contained in the study (completed using a commercial spreadsheet program -- it is identical to Table 1 in Appendix B). Table 2 contains the exposures, doses, and MOEs attributable to bensulide exposure for toddlers completing activities on turf at the lowest and highest allowable application rates (i.e., lowest rate values were calculated using a simple proportion and the study data which were developed at the highest application rate). High exposure activities for children were only considered in this assessment. Table 3 is essentially the same as Table 2 except that both bensulide and bensulide oxon residues are considered in the assessment.

The Food Quality Protection Act requires that the Agency aggregate (or add together) exposures that can occur in a variety of different ways to a chemical. The previous assessments that were completed for bensulide focused only on dermal exposures that could occur for adults during yardwork and activities such as golfing, and for children after contact with treated turf during

heavy play activities. The previous exposure assessments were unrefined because no chemical- and scenario-specific data were available and the Agency used standard approaches in lieu of data. The results of these previous assessments indicated that the Agency had concerns when just dermal exposures were considered. Therefore, no attempt was made to calculate exposures from other sources as it was known that refinements to the risk assessment were already needed and no attempt was made to aggregate the exposures from more than one source of nondietary exposure

The data from this study are the basis for the present, more refined, exposure assessment that has been completed for bensulide uses on turf. In this refined assessment, the Agency has considered children's exposures that can occur to the skin as well as exposures that may occur via sporadic behaviors such as mouthing treated grass or from hand-to-mouth activity (i.e., referred to as non-dietary exposures). The Agency has taken this approach in this more refined assessment because the exposure levels are within a range where aggregation of exposures from more than one source (i.e., dermal and non-dietary ingestion) is appropriate. The Agency has developed a document that is used by exposure assessors called the SOPs For Residential Exposure Assessments that was completed in December, 1997. This document contains guidance for considering children's exposure to treated turf. The dermal calculations, as noted above, were completed based on the guidance provided in the document. All nondietary exposures were also calculated using guidance from this document. Specifically, the kinds of nondietary exposures that were considered in this assessment include the following:

- □ Dose from hand to mouth activity calculated using SOP 2.3.2: Postapplication potential dose among toddlers from incidental nondietary ingestion of pesticide residues on residential lawns from hand-to-mouth transfer (i.e., those residues that end up in the mouth from a child touching surfaces then putting their hands in their mouth); and
- □ Dose from mouthing treated turf calculated using SOP 2.3.3: Postapplication potential dose among toddlers from the ingestion of pesticide treated turfgrass (i.e., residues that end up in the mouth after a child actively mouths turf a handful of turf).

The following illustrates the basics of the approach, used to calculate exposures that are attributable to a child touching treated turf and then putting their hands in their mouth (SOP 2.3.2):

$$D = (TTR * SA * Freq * Hr * (1mg/1000\mu g))$$

where:

D = dose from hand-to-mouth activity (mg/day);

TTR(t)= Turf Transferable Residue at time (t) where the longest

duration (t) is dictated by the kinetics observed in the

TTR study (μ g/cm²);

SA = surface area of the hands (cm²);

Freq = frequency of hand-to-mouth events (events/hour); and

Hr = exposure duration (hours).

As indicated above, the turf transferable residue represents the amount of chemical on the surfaces of treated leaves that can rub off on one's skin. The data from the Gowan TTR study referenced above is used in this risk assessment. The surface area for hands used (350 cm²) is the median surface area for a toddler (age 3 years) as described in the SOPs For Residential Exposure Assessment. The time spent outdoors (2 hours/day) and frequency of events (1.56 events/hour) are referenced directly from the SOPs For Residential Exposure Assessment. The 2 hour duration value is also a recommended value from the U.S. EPA Exposure Factors Handbook (U.S. EPA, 1997). This model for hand-to-mouth dose is based on the premise that a child puts both of their hand entirely in their mouths, the residues on the hands are completely transferred from the hands to the mouth, and that all of the residues available on the treated turf transfer to the child's hand each time they exhibit this behavior.

The following illustrates the basics of the approach, used to calculate exposures that are attributable to a child mouthing treated turf (SOP 2.3.3):

$$D = (TTR * IgR * (1mg/1000\mu g))$$

where:

D = dose from mouthing activity (mg/day);

TTR(t) = Turf Transferable Residue (TTR) at time (t) where the longest duration (t) is dictated by the kinetics observed in the TTR study (μ g/cm²); and

IgR = ingestion rate for mouthing of grass per day (cm²/day).

As indicated above, the turf transferable residue represents the amount of chemical on the surfaces of treated leaves that can rub off on one's skin or, as in this case, that can transfer from mouthing of turf. The data from the Gowan TTR study referenced above are used in this risk assessment. The ingestion rate used (25 cm²/day) assumes that over the course of a day. This model for a mouthing behavior dose is based on the premise that a child will grab a handful of turf, mouth it and remove all bensulide residues, and then remove it from their mouth as described in the SOPs For Residential Exposure Assessment. The surface area of (25 cm²/day) is thought to approximate a handful of turf that is mouthed.

The results of the nondietary exposure calculations are presented in Appendix C. Table 1 contains the kinetics analysis of the TTR data contained in the study (completed using a commercial spreadsheet program). Tables 2 and 3 contain the exposures, doses, and MOEs attributable to dermal exposure as indicated above. Tables 4 and 5 contain the nondietary exposures, doses, and MOEs attributable to hand-to-mouth activity. Table 4 addresses hand-to-mouth activity calculated for bensulide residues only while Table 5 addresses hand-to-mouth activity calculated for both bensulide and bensulide oxon residues. Tables 6 and 7 contain the nondietary exposures, doses, and MOEs attributable to mouthing treated turf. Table 6 addresses the mouthing risks calculated for bensulide residues only while Table 7 addresses the mouthing risks calculated for both bensulide and bensulide oxon residues.

The following specific assumptions and factors were used in order to complete this exposure assessment:

- □ These assessments were based on the guidance provided, as appropriate, in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)* and the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*. Several of the assumptions and factors used in the exposure assessment are described in that document. [Note: The Agency is bringing the SOPs For Residential Exposure Assessment before the FIFRA Science Advisory Panel in July of this year. This may resolve and refine several of the approaches used by the Agency for residential exposure assessment.]
- □ Calculations are completed at the minimum and maximum application rates recommended by the available bensulide labels to bracket risk levels associated with the various use patterns and activity scenarios. No use data were provided by the registrant concerning actual application rates. The minimum application rate is based on Reg. No.10163-204-33955 while maximum application rate is based on Reg. No. 10163-198-2217 (as well as several others).
- Due to a lack of scenario-specific exposure data, HED has calculated exposure values for adults using surrogate dermal transfer coefficients that represent reasonable low (1,000 cm²/hour) and high exposure activities (10,000 cm²/hour) such as mowing, golfing, and yardwork. [Note: The transfer coefficient prescribed in the residential SOPs for this scenario for adults is 43,000 cm²/hour. Lower transfer coefficient values were selected for this assessment (i.e., 1,000 and 10,000 cm²/hour) so that the dose levels could also be used by the Agency also for the occupational assessment. Based on the residential SOPs, a transfer coefficient of 8,700 cm²/hour was used to calculate dermal exposures for toddlers. [Note: The toddler exposures are conservative because the transfer coefficients are based on the Jazzercise protocol and an upper percentile exposure duration value.]

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

No agency-based modifications are included in this aspect of the assessment except for the fact that the 21 day dermal toxicity study serves as the basis for the risk assessment and that the nondietary ingestion pathways have been added to address toddler exposures. Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998.

Several of the comments provided by the Gowan Chemical Company in their RED rebuttal discussed the appropriateness of completing intermediate-term risk assessments on turf. The turf transferable residue dissipation and 21 day dermal toxicity studies submitted by the Gowan Chemical Company alleviated these comments.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency has attempted to address all comments and to make a general overall attempt towards more transparency in this risk assessment.

b. Occupational and Residential Risk Assessment/Characterization

The results of the risk assessment that has been completed for bensulide are included in this section of the document. Also presented below are the methods used to calculate risks, a characterization of the risks, and issues that have been identified in the interpretation of the calculated risks. The risks are summarized below based on the category of the risk assessment (e.g., postapplication occupational worker).

(1) Methods For Calculating Risks From Calculated Exposures

The exposures that were calculated in section 4.a. above represent the amount of bensulide that can be deposited on the surface of the skin during or after application, that can be inhaled

during application, or that can be attributed to the mouthing behaviors of children after contact with treated turf. The Agency has commonly used the term "exposure" to refer to these calculated values. For consistency, the Agency has also used the term "dose" to refer to the levels of pesticide residues after an appropriate absorption factor has been considered (e.g., through the skin) and the exposures have been normalized (divided by) the appropriate body weight to obtain dose levels in units of (mg/kg/day). The Agency calculates dose levels using the following:

Daily Dose
$$\left(\frac{mg\ ai}{kg/day}\right)$$
 = Daily Exposure $\left(\frac{mg\ ai}{day}\right)$ $\times \left(\frac{AbsorptionFactor(\%/100)}{Body\ Weight\ (kg)}\right)$

Where:

Daily Dose = the amount as potential dose (for the dermal

calculations) or absorbed dose (for inhalation or nondietary ingestion

calculations) received from exposure to a pesticide in a given scenario (mg pesticide

active ingredient/kg body weight/day);

Daily Exposure= the amount of dermal (on the skin),

inhalation (inhaled), or nondietary ingestion (from mouthing behaviors of children) exposure calculated above in section 4.a

(mg pesticide active ingredient/day);

Absorption Factor= a measure of the flux or amount of chemical

that crosses a biological boundary (% of the

total available); and

Body Weight = body weight determined to represent the

population of interest in a risk assessment

(kg).

[Note: The U.S. EPA Exposure Assessment Guidelines (EPA, 1992) define potential dose as the amount of a chemical at the absorption barrier. Additionally, absorbed dose is defined as the amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors.]

For bensulide, the average body weight for adults used in all assessments is 70 kg which is a value commonly used in risk

assessment. The average body weight for toddlers used in all assessments is 15 kg based on the *SOPs For Residential Exposure Assessment*. In this assessment, the use of a dermal absorption factor is not required since a 21 day dermal administration toxicity study was selected as the source for the endpoint. Absorption from inhalation and nondietary ingestion are 100 percent, the standard Agency value used for these scenarios.

After dose levels have been calculated, the next step is to calculate a Margin of Exposure (MOE) value. MOEs are used by the Agency to represent risks. A Margin of Exposure can be thought of as a measure of how close (i.e., the margin) exposures are to a concern based on the toxicity of a chemical. The level of concern for regulatory action (can be thought of as an acceptability trigger) is established by or equivalent to the uncertainty factors that are decided upon in the hazard assessment process (toxicity data evaluation) and in the consideration of the additional safety factor required by the *Food* Quality Protection Act. The combined uncertainty factor that applies to all bensulide risk assessments is 100 (see Section 4.a.2 above). The NOAELs (No Observed Adverse Effect Level) used for each risk assessment is also presented in Section 4.a.2 above. Dermal MOEs were calculated using a NOAEL of 50 mg/kg/day. Short-term inhalation MOEs were calculated using a NOEL of 5.5 mg/kg/day and the intermediate-term inhalation MOEs were calculated using a NOEL of 0.5 mg/kg/day. All oral (nondietary ingestion) MOEs were calculated using a NOAEL of 15 mg/kg/day. MOEs, regardless of the exposure scenario or toxicity endpoint, were calculated using the following formula:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Where:

MOE = margin of exposure or value used by the Agency to represent the risk, how close a chemical

exposure is to being a concern, associated with a chemical exposure (unitless);

Daily Dose=

the amount as potential dose (for the dermal calculations) or absorbed dose (for inhalation or nondietary ingestion calculations) received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and

NOAEL = dose level in a toxicity study where no observed adverse effects occur (mg pesticide active ingredient/kg body weight/day).

In order for the Agency to make more informed risk management decisions, MOEs can be added together in order to look at the aggregate exposures that occur for an individual if the toxic effect for each route of exposure (e.g., to the skin and being inhaled) is the same. For example, combining dermal and oral nondietary ingestion MOEs for children is of interest because these exposures can occur at the same time. Additionally, combining exposures for growers who both mix/load and apply bensulide using groundboom sprayers (they are calculated separately in the assessment in Section 4.a) would be logical because it is likely that in most farms the same individual would be completing both of these tasks. The equation the Agency uses to add MOEs together is presented below:

$$MOE_{total} = 1/((1/MOE_a) + (1/MOE_b) + (1/MOE_n))$$

Where: MOE_a , MOE_b , and MOE_n represent MOEs for each exposure route of concern

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

No agency-based modifications are included in this aspect of the assessment except for the fact that the 21 day dermal toxicity study serves as the basis for the risk assessment, nondietary ingestion pathways have been added to address toddler exposures, and the summary of the handler risks is presented in a different manner to address route-specific and overall risks for varying scenarios. Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998.

Several of the comments provided by the Gowan Chemical Company in their RED rebuttal discussed the appropriateness of completing intermediate-term risk assessments on turf. The turf transferable residue dissipation and 21 day dermal toxicity studies submitted by the Gowan Chemical Company alleviated these comments.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency has attempted to address all comments and to make a general overall attempt towards more transparency in this risk assessment.

(2) General Risk Characterization Considerations

Several issues must be considered when interpreting the occupational and residential exposure (ORE) and risk assessment. These include:

- No chemical-specific exposure data were submitted. As a result, all analyses were completed using surrogate data from sources such as PHED and assumptions related to the behaviors of adults and children in a previously treated environment (e.g., transfer coefficients for adults and children on turf). The values that have been used are consistent with agency policy. The Agency has developed a policy that specifies standard values for transfer coefficients to be used in lieu of data. It is likely that the transfer coefficients may be refined upon completion of the work of the reentry task forces currently ongoing within the industry.
- The data from a recent, state-of-the-art, turf transferable residue study were used in the postapplication exposure assessment. These data have added significant refinement to the assessment.
- ☐ The Agency always considers the maximum application rates allowed by labels in its risk assessments (cancer assessments are the exception) in order to be able to consider what is legally possible based on the label in order to ensure proper stewardship. If more information is

available concerning the use patterns of the chemical, the Agency tries to incorporate it into the risk assessment process. Use and usage data were not available for bensulide to establish average application rates which would also be used in the risk assessment along with maximum label application. However, minimum application rates were specified on the label so these values were also used in the assessment in conjunction with the maximum values allowed by bensulide labels. The largest difference between the minimum and maximum application rates, for a bensulide market, was a factor of 2 which was for the agricultural uses of bensulide (i.e., rates ranged from 3 to 6 pounds of active ingredient per acre).

- Several handler assessments were completed using "low quality" PHED data due to the lack of a more appropriate dataset.
- □ Several generic protection factors were used to calculate handler exposures. These protection factors have not been completely evaluated and accepted by the Agency for gloves and additional layers of clothing. The Agency is currently engaged in a project through NAFTA (North American Free Trade Agreement) auspices to develop harmonized values for risk assessment purpose. The protection factors used for respirator use are the standard values stipulated by NIOSH and through OSHA.
- Exposure factors used to calculate daily exposures to handlers and for the post-application scenarios (e.g., hours per day for occupational post-application exposure or acres treated per day for each application method) are based on the best professional judgement due to a lack of data. In other cases, exposure factors have been referenced from highly refined sources such as the U.S. EPA Exposure Factors Handbook. In instances where exposure factors have been referenced from sources such as the Exposure Factors Handbook, they are noted individually.
- According to the registrant, watering in of bensulide is a requirement for efficacy purposes on turf. The turf transferable residue dissipation study completed by the Gowan Chemical Company included a watering-in irrigation

event on the day of application. Whether or not this requirement is followed (and added to all labels if it does not already exist on all labels), impacts the interpretation of the risk assessment (i.e., MOEs are not a concern after watering in but are less than 100 in some cases prior to watering in). The other factor that needs to be considered is that the Agency completes risk assessments based on the label directions for a product and not uses which are not completed per label instructions.

- One of the major criticisms of the previous risk assessments completed for bensulide has been the intermediate-term risk assessments. The acceptance by the Agency of the 21 day dermal toxicity study (it is appropriate for both short- and intermediate-term exposures) has alleviated this issue related to dermal exposures, which are predominant. However, the Agency still considers both short- and intermediate-term inhalation exposures in the risk assessment. It is likely that most bensulide exposures are probably short-term in nature because of the way that bensulide is used. There is, however, still a potential for intermediate-term inhalation exposures. For example, a professional applicator treating large acreages over weeks or a golf course applicator treating a course over a few weeks could be exposed in an intermediate-term pattern. No acceptable use and usage information has been provided to the Agency to address this issue. The use and usage issue has also been presented to the Agency's Tolerance Reassessment Advisory Committee for consideration as science policy issue. Resolution of the policy issue may refine the assessment related to the intermediate-term exposures considered herein.
- ☐ The acres per day values used in the handler risk assessments are the standard values that have been used by the Agency for several years. They essentially concur with data contained in the Pesticide Handlers Exposure Database. They also essentially concur with the values included in the draft project through NAFTA that is intended to produce internationally harmonized values for risk assessments.

Refinement of the ORE exposure and risk assessment calculations presented in this chapter is possible if the issues presented above are addressed by the registrant or if more refined approaches or data become available to HED.

Modifications Based on Agency Revisions, USDA Comments, and/or Gowan Comments

No agency-based modifications are included in this aspect of the assessment except for the fact that the 21 day dermal toxicity study serves as the basis for the risk assessment, nondietary ingestion pathways have been added to address toddler exposures, and the summary of the handler risks is presented in a different manner to address route-specific and overall risks for varying scenarios. Additionally, no changes to the assessment were included in this section as a result of the Agency accepting Gowan comments to the initial RED document of March, 1998.

Several of the comments provided by the Gowan Chemical Company in their RED rebuttal discussed the appropriateness of completing intermediate-term risk assessments on turf. The turf transferable residue dissipation and 21 day dermal toxicity studies submitted by the Gowan Chemical Company alleviated these comments.

The Agency, in response to the United States Department of Agriculture comments, attempted to further describe the origins of the critical factors used in this risk assessment including: exposure factors; use and usage information; and exposure data. In particular, the Agency has attempted to address all comments and to make a general overall attempt towards more transparency in this risk assessment.

(3) Occupational and Residential Handler Risk Summary

In this current assessment, which is based on a different approach from the previous assessments completed for bensulide, risks for handlers were assessed using separate toxicological endpoints for both dermal and inhalation exposures. The resulting risks (MOE values) were then added in order to obtain an overall risk for each applicator that accounted for both dermal and inhalation exposures. Additionally, where it was logical, the risks associated with certain job functions were combined (e.g., a grower mixing/loading and then applying a spray solution to their own crops). Dermal and inhalation risks are mitigated using different types of protective equipment so it may be acceptable to add a pair of gloves and not a respirator,

and vice versa. All of the risk calculations for handlers completed in this assessment are included in Appendix A.

The specifics of each of table included in Appendix A is described below:

- ☐ Table 1: Input Parameters For Bensulide Handler Exposure and Risk Calculations Presents the exposure values and other exposure factors used in the risk assessment.
- □ Table 2: Bensulide Handler Exposure and Risk
 Calculations At The Baseline Protection Level
 Represents typical work clothing or a long-sleeved shirt and long pants with no respiratory protection. No chemical-resistant gloves are included in this scenario (a couple scenarios have gloves -- see notes on Table 6). This table also includes the risk assessment for homeowner handlers which are assumed to wear short pants and a short-sleeved shirt. [Note: The calculations from this table have been used to develop the summary in Table 9.]
- ☐ Table 3: Bensulide Handler Exposure and Risk
 Calculations At The Minimum PPE Protection Levels
 Represents the baseline scenario with the use of chemicalresistant gloves and respirators. [Note: The calculations
 from this table have been used to develop the summary in
 Table 9.]
- □ Table 4: Bensulide Handler Exposure and Risk
 Calculations At The Maximum PPE PPE Protection
 Levels Represents the baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and, in some cases, a respirator.
 [Note: The calculations from this table have been used to develop the summary in Table 9.]
- ☐ Table 5: Bensulide Handler Exposure and Risk
 Calculations At The Engineering Control Protection
 Levels Represents the use of an appropriate engineering
 control such as a closed tractor cab or closed loading
 system for granulars or liquids. Engineering controls are not
 applicable to handheld application methods there are no

known devices that can be used to routinely lower the exposures for these methods. [Note: The calculations from this table have been used to develop the summary in Table 9.]

- ☐ Table 6: Sources of Exposure Data Used in the Bensulide Handler Exposure and Risk Calculations

 Describes the sources of the exposure data used in all of the handler calculations.
- ☐ Table 7: Bensulide MOEs Attributable to Dermal

 Exposure Summarizes all MOEs calculated for dermal
 exposures at each level of personal protection (i.e., baseline
 through engineering controls). [Note: See tables 2 through 5
 for calculations of specific MOE values.]
- ☐ Table 8: Bensulide MOEs Attributable to Inhalation

 Exposure Summarizes all MOEs calculated for inhalation
 exposures at each level of personal protection (i.e., baseline
 through engineering controls). [Note: See tables 2 through
 5 for calculations of specific MOE values.]
- □ Table 9: Bensulide MOEs Attributable to Combined Dermal and Inhalation Exposures When Respirators Are Used In Conjunction With The Baseline and PPE Clothing Scenarios Presents combined dermal and inhalation MOEs with each possible combination of dermal and respiratory protection considered in this assessment (both short- and intermediate-term exposures). [Note: See tables 2 through 5 for calculations of specific MOE values.]
- ☐ Table 10: Bensulide MOEs Attributable to Combined Job Functions Presents combined risks for growers and golf course workers who mix/load and apply bensulide using groundboom sprayers or tractor drawn spreaders.

Tables 1 through 6 of Appendix A can be used to illustrate how the calculations were performed to define the MOEs for handlers in this risk assessment. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from bensulide labels, the exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but the best available, data.

Tables 7 and 8 provide summaries of the MOE values calculated for each route of exposure, dermal and inhalation, respectively, in the risk assessment. Tables 9 and 10 provide the information that are the key to interpreting the overall results of the risk assessment because they contain the overall risks calculated using several combinations of personal protection.

When protective measures are used to reduce risks it is appropriate to consider how each method will reduce the associated risks (e.g., gloves will reduce risks from dermal exposures by 90 percent based on the Agency protection factor for gloves). This is particularly important when route-specific (how the chemical enters the body) toxicity data are available, as is now the case for bensulide, because it allows for more flexibility in the risk management process (information presented in Appendix C/Tables 7 & 8). In addition, it is necessary to consider the combined risks for each scenario so that the risk management decision can be protective in an overall manner and also be based on the minimum level of personal protection from dermal and inhalation exposures. This is the key element in the risk assessment. The combined risks calculated for bensulide handlers are summarized below (Appendix A/Table 9). [Note: Appendix A/Table 10 also contains MOEs that have been calculated for individuals who do all job tasks related to an application event. These results are also separately summarized below.] For concerns over data quality or the sources of the data used to calculated each exposure value, see Appendix A/Table 6. The risks are summarized based on the specific markets for bensulide use and the lowest level of personal protection where the Agency has no concern (MOEs>100).

Generally, the Agency has little concerns over the use of bensulide in agriculture. The Agency does have some concerns over the uses of certain application methods for occupational uses on golf courses and in residential settings. It should be noted that intermediate-term inhalation exposures could be considered risk drivers in this assessment. In some cases, respiratory protection can alleviate this concern. However, in other cases, the use of respiratory protection in some occupational settings is not sufficiently protective. The Agency is also concerned about the use of a bellygrinder by homeowners to treat residential turf. A range of MOEs are also presented for

each scenario where the range is based on the minimum and maximum application rates for the scenario.

For Occupational Uses on Turf and Ornamentals:

- (1b) mixing/loading liquids for groundboom application to golf courses (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 206 to 344); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 200 to 333).
- (1c) mixing/loading liquids for professional turf applications (50 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 165 to 275); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 160 to 267).
- (2) treating an entire golf course for loading granulars for tractor-drawn spreader application (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing, no gloves, and no respirator are required (MOEs 293 to 489); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 293 to 488).
- (3) treating an entire golf course for applying sprays with a groundboom sprayer (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing and no respirator are required (MOEs 338 to 562); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 327 to 545).
- (4) treating an entire golf course applying granulars with a tractor-drawn spreader (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing and no respirator are required (MOEs 335 to 558); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 365 to 608).

- (5) 7 acres of greens and tees or 5 acres of residential lawns, mixing/loading/applying with a low pressure handwand: on golf courses, when dermal exposures are combined with short-term inhalation exposures/double layer clothing, gloves and a respirator are required (MOEs 101 to 168); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even though dermal exposures could be mitigated (MOEs 60 to 100); on residential turf, when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 123 to 204); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even though dermal exposures could be mitigated (MOEs 84 to 139).
- (6) 1000 gallons for golf courses (greens and tees) and residential lawns for mixing/loading/applying with a high pressure handwand: on golf courses and on residential turf, when dermal exposures are combined with short-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOE 13); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOE 8).
- (7) 7 acres of greens and tees or 5 acres of residential lawns for mixing/loading/applying with a backpack sprayer: on golf courses and on residential turf, when dermal exposures are combined with short-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 12 to 57); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 8 to 49).
- (8) 7 acres of greens and tees 5 acres of residential lawns for mixing/loading/applying with a low pressure/high volume turf handgun: on golf courses, when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 104 to 174); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 104 to 173); on residential turf, when dermal exposures are combined with short-term inhalation

exposures/single layer clothing, gloves and no respirator are required (MOEs 146 to 243); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 145 to 242).

- (9) 5 acres of residential lawns for loading/applying with a push-type granular lawn spreader: on residential turf, when dermal exposures are combined with short-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 79 to 132); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 73 to 122).
- (10) 5 acres of residential lawns for loading/applying with a bellygrinder: on residential turf, when dermal exposures are combined with short-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 10 to 16); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency still has concerns even at the maximum level of mitigation (MOEs 9 to 15).

For Occupational Uses In Agriculture:

(1a) 40 and 350 acres for mixing/loading liquids for chemigation application: applying to only 40 acres as suggested by the registrant, when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves, and no respirator are required (MOEs 430 to 860); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 102 to 204); applying to only 350 acres using standard Agency value for area treated, when dermal exposures are combined with short-term inhalation exposures/engineering controls are required (MOEs 178 to 356); and when dermal exposures are combined with intermediate-term inhalation exposures/the Agency has minimal concerns even at the maximum level of mitigation (MOEs 98 to 197).

- (1b) 80 acres for mixing/loading liquids for groundboom application: when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves, and no respirator are required (MOEs 215 to 430); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 208 to 417).
- (3) 80 acres for applying sprays with a groundboom sprayer: when dermal exposures are combined with short-term inhalation exposures/single layer clothing, no gloves, and no respirator are required (MOEs 352 to 704); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 341 to 682).

For Residential Uses by Homeowners:

- (9) 0.5 acres for loading/applying with a push-type granular lawn spreader: when dermal exposures are combined with short-term inhalation exposures and individuals wear short pants and short sleeved shirts, the Agency has no concerns (MOEs 183 to 305).
- (10) 0.5 acres for loading/applying with a bellygrinder: when dermal exposures are combined with short-term inhalation exposures and individuals wear short pants and short sleeved shirts, the Agency has concerns over this use (MOEs <10).

For some jobs such as groundboom applications in agriculture or on golf course turf, it is logical that a percentage of the individuals will participate in all aspects of the application process and not just perform mixing/loading or the application parts of the process. The job functions/tasks that were combined include:

For Occupational Uses on Turf and Ornamentals:

(1b& 3) mixing/loading liquids for groundboom application to golf courses (40 acres treated) and treating an entire golf course for applying sprays with a groundboom sprayer (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 128 to 213); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 124 to 207).

(2 & 4) loading and treating an entire golf course with granulars using a tractor-drawn spreader application (40 acres treated): when dermal exposures are combined with short-term inhalation exposures/single layer clothing, no gloves, and no respirator are required (MOEs 156 to 261); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 162 to 271).

For Occupational Uses In Agriculture:

(1b& 3) mixing/loading liquids for groundboom application to agricultural sites and treating 80 acres treated with a groundboom sprayer: when dermal exposures are combined with short-term inhalation exposures/single layer clothing, gloves and no respirator are required (MOEs 134 to 267); and when dermal exposures are combined with intermediate-term inhalation exposures/single layer clothing, gloves and a respirator are required (MOEs 129 to 259).

The calculations completed by the Agency for these exposures are presented in Appendix A/Table 10. The results of this analysis indicate that the level of personal protection required for the mixing/loading aspects of the process is appropriate for the entire application if job functions or tasks are combined.

(4) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures in agriculture as well as exposures that can occur as a result of turf management activities. The results of each assessment is presented below. All of the risk calculations for handlers completed in this assessment are included in Appendix B. The specifics of each of table included in Appendix B is described below:

- ☐ Table 1: Analysis of Bensulide Turf Transferable
 Residue (TTR) Data Presents the values used in the
 analysis excerpted from the TTR study submitted by the
 Gowan Company and the results of the regression analyses
 completed with the data.
- □ Table 2: MOEs Attributable to Bensulide Exposure For Adults Engaged in Activities on Treated Turf Presents the MOEs that were calculated for adult post-application exposures involved in both light and heavy activities at the lowest and highest application rates. These values have been used in both the occupational and residential risk assessments as described above. The calculations are based only on the presence of bensulide residues. Bensulide oxon residues have not been considered in this assessment.
- □ Table 3: MOEs Attributable to Bensulide and Bensulide Oxon Exposure For Adults Engaged in Activities on Treated Turf Presents the MOEs that were calculated for adult post-application exposures involved in both light and heavy activities at the lowest and highest application rates. These values have been used in both the occupational and residential risk assessments as described above. The calculations are based on the presence of both bensulide and bensulide oxon residues.

For Occupational Uses In Agriculture:

Given the current state of knowledge, HED does not consider post application exposure in agricultural settings problematic due to the cultivation practices that are anticipated with the preplant/pre-emergent use of bensulide on the labelled agricultural crops (i.e., the WPS prescribed reentry interval is adequate). This evaluation is based on an assessment of bensulide labelling and available use information. However, HED requests that additional information be submitted pertaining to cultural practices of the labelled crops in order to refine this assessment. The Agency has taken this position even though the United States Department of Agriculture comments indicated "in most transplanting operations, transplants are placed into the soil by mechanical planters. Workers generally place plants into a mechanical wheel that rotates and places plants into the soil. These individuals do not come into contact with treated soil." The Agency agrees that these workers likely do not have extensive contact with treated soil. They do, however, have extensive contact with the transplant wheel that does have extensive contact with the soil. This contact could result in the exposure that the Agency is concerned about.

For Occupational Uses on Turf and Ornamentals (*+):

Post-application occupational risks related to the use of bensulide on turf were calculated for individuals involved in turf management activities such as golf course greens keepers and landscaping personnel. Two types of activities considered in this assessment (as presented in Section 4.a) are presented below:

- (i) adults involved in a low exposure activity, such as moving cups on golf course greens, at the lowest prescribed application rate for turf (i.e., dose levels are equal to residential adult scenario 1); and
- (ii) adults involved in a high exposure activity, such as heavy weeding or other turf management activity, at the highest application rate for turf (i.e., dose levels are equal to residential adult scenario 2).

The Agency uses an administrative method of risk mitigation for addressing risks from post-application exposures in an occupational setting called the *Restricted Entry Interval (REI)*. REIs are essentially the amount of time it takes for residues in the work environment to dissipate to a level that allows for jobs or tasks to be completed without a concern for chemical exposure. REIs are generally considered by the Agency on a chemical- and job/task-specific basis. In the previous assessments completed

without the new bensulide-specific turf transferable residue (TTR) and dermal toxicity data, the REIs predicted for adults involved in a low exposure activity at the lowest prescribed application rate was 29 days after application. The REIs predicted for adults involved in a high exposure activity at the highest prescribed application rate was 55 days after application.

In the turf transferable residue study, bensulide was applied. TTRs were sampled, the bensulide was watered in per label directions (~0.5 inches of water), and TTRs were sampled again on the day of application. Samples were also collected out to 35 days after application but bensulide residues declined to below the limit of quantitation after about 14 days. The Agency analyzed these data with the standard approaches for kinetics then calculated risks based on predicted values. Risks were also calculated using the actual measured values. The Agency recommends that, based on the data in this study, that the actual measured values are a better risk predictor because of the significant dissipation that occurred on the day of and also on the day after application. Therefore, predicted values are not appropriate for use in the risk assessment because the most significant dissipation occurs quickly after application and there is insufficient data to develop a predictive residue model, particularly given the consideration that three sets of measured data were collected over this time interval of interest.

The results of this assessment are more refined (because of the recently submitted data) and significantly different from the previous assessment (all calculations and results are presented in Appendix B/Tables 1 through 3). Following the watering in of bensulide (keeping in mind the monitoring study used about 0.5 inches of water for irrigation) MOEs are greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate (occupational post-application scenario 2). If the watering in was not as extensive (0.5 inches) as completed in the study (i.e., using the pre-watering in monitoring data), MOEs are still greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate (occupational post-application scenario 2). The completion of separate shortand intermediate-term risk assessments for occupational bensulide post-application exposures is no longer appropriate because the selected 21 day dermal toxicity endpoint is

applicable to both durations of exposure and the exposure values themselves, that would be used if separate assessments were completed, are the same (i.e., each separate assessment would be exactly the same so one was completed that is representative of both durations). The following table summarizes the results:

Table 11. Summary of Critical MOEs For Adult Post-application Exposures to Bensulide and Bensulide Oxon

Time	Dermal Exposures For Light Activity & Lowest Application Rate	Dermal Exposures For Heavy Activity & Highest Application Rate
Day of application prior to watering in	2600	150
Day of application after watering in	8300	480

MOEs > 100 are not a concern to the Agency, Application rates considered are 7.5 and 12.5 pounds of active ingredient per acre. This table was developed based on the calculations presented in Appendix B/Table 3 (actual monitoring data).

(5) Post-Application Residential Risks

The use of a Restricted Entry Interval is not an appropriate method of risk mitigation for residential use chemicals and, essentially, for all exposure scenarios where there is the potential for unrestricted general population exposures. As a result, the approach used to evaluate residential risks is to consider exposures immediately after application as these represent higher exposures and risks which are a concern for acutely toxic compounds like the organophosphates.

Bensulide can be used in a residential setting and it can also be used on golf courses (and on other turf) where exposures to the general population can occur. As a result, both toddler and adult risks were considered in this assessment. The dose levels and MOEs used in this risk assessment for adults are the same values that were calculated and presented for the occupational post-application scenarios presented in Appendix B and in Section 4.b.4 above. The same adult dose levels were used for both assessments because no activity-specific transfer coefficients were available to address all of the exposure scenarios considered in this assessment. The transfer coefficients that were used in the assessment generally can be used to equally describe all of the exposures considered. All

residential post-application risk calculations completed for children are presented in Appendix C of this document.

The specifics of each of table included in Appendix C is described below:

- □ Table 1: Analysis of Bensulide Turf Transferable
 Residue (TTR) Data Presents the values used in the
 analysis excerpted from the TTR study submitted by the
 Gowan Company and the results of the regression analyses
 completed with the data. [Identical table also contained in
 Appendix B.]
- □ Table 2: Dermal Risks From Bensulide Attributable to Contact With Treated Turf Presents the MOEs that were calculated for the post-application dermal exposures of children involved in heavy contact activities at the lowest and highest application rates. The calculations are based only on the presence of bensulide residues. Bensulide oxon residues have not been considered in this assessment.
- ☐ Table 3: Dermal Risks From Bensulide and Bensulide Oxon Attributable to Contact With Treated Turf

 Presents the MOEs that were calculated for the postapplication dermal exposures of children involved in heavy contact activities at the lowest and highest application rates.

 The calculations are based on the presence of both bensulide and bensulide oxon residues.
- □ Table 4: Risks Attributable to Bensulide Residues From Mouthing Bensulide Treated Turf Presents the MOEs that were calculated for the post-application nondietary ingestion exposures of children due to mouthing treated turf, as described in SOP 2.3.3 of the Agency's SOPs For Residential Exposure Assessment, at the lowest and highest application rates. The calculations are based only on the presence of bensulide residues. Bensulide oxon residues have not been considered in this assessment.
- □ Table 5: Risks Attributable to Bensulide and Bensulide Oxon Residues From Mouthing Bensulide Treated Turf Presents the MOEs that were calculated for the post-application nondietary ingestion exposures of children due to mouthing treated turf, as described in SOP 2.3.3 of the Agency's SOPs For Residential Exposure Assessment, at the lowest and highest application rates. The calculations are based on the presence of both bensulide and bensulide oxon residues.

- □ Table 6: Risks Attributable to Bensulide Residues From Hand-to-Mouth Activity on Bensulide Treated Turf
 Presents the MOEs that were calculated for the postapplication nondietary ingestion exposures of children due to hand-to-mouth activity on treated turf, as described in SOP 2.3.2 of the Agency's SOPs For Residential Exposure Assessment, at the lowest and highest application rates. The calculations are based only on the presence of bensulide residues. Bensulide oxon residues have not been considered in this assessment.
- □ Table 7: Risks Attributable to Bensulide and Bensulide
 Oxon From Hand-to-Mouth Activity on Bensulide
 Treated Turf Presents the MOEs that were calculated for
 the post-application nondietary ingestion exposures of
 children due to hand-to-mouth activity on treated turf, as
 described in SOP 2.3.2 of the Agency's SOPs For
 Residential Exposure Assessment, at the lowest and highest
 application rates. The calculations are based on the
 presence of both bensulide and bensulide oxon residues.

For Residential Adults:

Post-application risks for adults in a residential setting were calculated for individuals involved in light exposure activities such as golfing and also in heavy exposure activities such as heavy yardwork. Two types of activities considered in this assessment (as presented in Section 4.a) are presented below:

- (i) adults involved in a low exposure activity, such as golfing, at the lowest prescribed application rate for turf (i.e., dose levels are equal to occupational adult scenario 1); and
- (ii) adults involved in a high exposure activity, such as heavy yardwork, at the highest application rate for turf (i.e., dose levels are equal to occupational adult scenario 2).

In the turf transferable residue study, bensulide was applied, TTRs were sampled, the bensulide was watered in per label directions (~0.5 inches of water), and TTRs were sampled again on the day of application. Samples were also collected out to 35 days after application but bensulide residues declined to below the limit of quantitation after about 14 days. The Agency

analyzed these data with the standard approaches for kinetics then calculated risks based on predicted values. Risks were also calculated using the actual measured values. The Agency recommends that, based on the data in this study, that the actual measured values are a better risk predictor because of the significant dissipation that occurred on the day of and also on the day after application. Therefore, predicted values are not appropriate for use in the risk assessment because the most significant dissipation occurs quickly after application and there is insufficient data to develop a predictive residue model, particularly given the consideration that three sets of measured data were collected over this time interval of interest.

The results of this assessment are more refined (because of the recently submitted data) and significantly different from the previous assessment (all calculations and results are presented in Appendix B/Tables 1 through 3). Following the watering in of bensulide (keeping in mind the monitoring study used about 0.5 inches of water for irrigation) MOEs are greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate. If the watering in was not as extensive (0.5 inches) as completed in the study (i.e., using the pre-watering in monitoring data), MOEs are still greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate. The completion of separate short- and intermediate-term risk assessments for residential bensulide post-application exposures is no longer appropriate because the selected 21 day dermal toxicity endpoint is applicable to both durations of exposure and the exposure values themselves, that would be used if separate assessments were completed, are the same (i.e., each separate assessment would be exactly the same so one was completed that is representative of both durations). The TTR study data also indicate that bensulide also dissipates in a manner that is not conducive to the use of an intermediate-term post-application risk assessment. The following table summarizes the results:

Table 12. Summary of Critical MOEs For Adult Post-application Exposures to Bensulide and Bensulide Oxon

Time	Dermal Exposures For Light Activity & Lowest Application Rate	Dermal Exposures For Heavy Activity & Highest Application Rate
Day of application prior to watering in	2600	150
Day of application after watering in	8300	480

MOEs > 100 are not a concern to the Agency, Application rates considered are 7.5 and 12.5 pounds of active ingredient per acre. This table was developed based on the calculations presented in Appendix B/Table 3 (actual monitoring data).

For Residential Toddlers:

Toddler risk levels were calculated based on the guidance provided in the SOPs for Residential Exposure Assessment and using both the minimum and maximum application rates, the recently submitted 21 day dermal toxicity study, and the recently submitted turf transferable residue study for bensulide. Toddlers have been selected as the age group of concern for this assessment because the Agency believes that this group has the highest potential for exposure because they routinely engage in play activities that involve heavy contact with turf, and they are likely to also exhibit mouthing behaviors that might contribute to nondietary ingestion exposures.

Post-application risks for toddlers in a residential setting were calculated for individuals involved in heavy exposure activities (represented by the Jazzercise-based transfer coefficient in the SOPs for Residential Exposure Assessment) at the minimum and maximum application rates for bensulide (Appendix C/Tables 2 and 3). Nondietary ingestion calculations considered two types of mouthing behaviors including turf mouthing (a child grabbing a handful of turf and mouthing it -- Appendix C/Tables 4 and 5) and hand-to-mouth behaviors (a child putting their dirty hands in their mouth -- Appendix C/Tables 6 and 7). It should be noted that non-dietary ingestion exposures are considered in this assessment and not in the previous assessments. This approach was used because the risks attributable to only dermal exposures indicated a concern to the Agency and the completion of the additional non-dietary calculations would have only indicated the same result -- that additional information for risk

assessment purposes was required. In this assessment, the dermal risks were not of the same magnitude as before because of the refinements based on the 21 day dermal toxicity study and the turf transferable residue study. The scenarios considered in this assessment (as presented in Section 4.a) are presented below:

- (3) toddlers involved in a high exposure activity at the lowest prescribed application rate for turf (i.e., dermal and nondietary ingestion calculations included); and
- (4) toddlers involved in a high exposure activity at the highest prescribed application rate for turf (i.e., dermal and nondietary ingestion calculations included).

In the turf transferable residue study, bensulide was applied, TTRs were sampled, the bensulide was watered in per label directions (~0.5 inches of water), and TTRs were sampled again on the day of application. Samples were also collected out to 35 days after application but bensulide residues declined to below the limit of quantitation after about 14 days. The Agency analyzed these data with the standard approaches for kinetics then calculated risks based on predicted values. Risks were also calculated using the actual measured values. The Agency recommends that, based on the data in this study, that the actual measured values are a better risk predictor because of the significant dissipation that occurred on the day of and also on the day after application. Therefore, predicted values are not appropriate for use in the risk assessment because the most significant dissipation occurs quickly after application and there is insufficient data to develop a predictive residue model, particularly given the consideration that three sets of measured data were collected over this time interval of interest.

The results of this assessment are more refined (because of the recently submitted data) and significantly different from the previous assessment (all calculations and results are presented in Appendix C/Tables 1 through 7). Following the watering in of bensulide (keeping in mind the monitoring study used about 0.5 inches of water for irrigation), the MOEs for dermal exposures were greater than 100 on the day of application even at the highest application rate for children in high exposure activities (e.g., hard play) over a long duration (SOPs use high percentile

duration value). If the watering in was not as extensive (0.5) inches) as completed in the study (i.e., using the pre-watering in monitoring data), MOEs for dermal exposures are still greater than 100 on the day of application for children in high exposure activities (e.g., hard play) over a long duration (SOPs use high percentile duration value) at the lowest application rate but not at the maximum application rate. The completion of separate shortand intermediate-term risk assessments for residential bensulide post-application exposures is no longer appropriate because the selected 21 day dermal toxicity endpoint is applicable to both durations of exposure and the exposure values themselves, that would be used if separate assessments were completed, are the same (i.e., each separate assessment would be exactly the same so one was completed that is representative of both durations). The TTR study data also indicate that bensulide also dissipates in a manner that is not conducive to the use of an intermediate-term post-application risk assessment. The following table summarizes the results:

Table 13. Summary of Critical MOEs For Child Post-application Exposures to Bensulide and Bensulide Oxon

Time	Dermal Exposures For Heavy Activity & Lowest Application Rate	Dermal Exposures For Heavy Activity & Highest Application Rate
Day of application prior to watering in	128	74
Day of application after watering in	410	237

MOEs > 100 are not a concern to the Agency, Application rates considered are 7.5 and 12.5 pounds of active ingredient per acre. This table was developed based on the calculations presented in Appendix C/Table 3 (actual monitoring data).

As indicated above, nondietary ingestion exposures were also considered in this assessment based on the approaches prescribed in the Agency's SOPs For Residential Exposure Assessment. Two specific SOPs (2.3.2 and 2.3.3) were considered in this assessment representing different kinds of behaviors. The SOPs provide guidance for estimating TTR values for use in an assessment in-lieu of chemical-specific data. In this assessment, chemical-specific data were available from the TTR study submitted by the Gowan Chemical Company. When these data are used instead of the generic approach, as is appropriate, the risks associated with the mouthing behaviors of

children are not a concern to the Agency. The interpretation of this result should also be considered with the fact that the Agency is bringing the *SOPs For Residential Exposure Assessment* back to the FIFRA Science Advisory Panel in July, 1999 for discussion

of this and other exposure issues -- the approaches used for the calculations included in this document may be modified based on the results of the SAP meeting. The MOEs that were calculated for nondietary ingestion are summarized in the following table:

Table 14. Summary of Critical MOEs For Child Post-application Exposures to Bensulide and Bensulide Oxon

Time	For Lowest Application Rate	For Highest Application Rate		
Exposures From Mouthing Treated Turf (Appendix C/Table 5)				
Day of application prior to watering in	26700	15500		
Day of application prior to watering in	85600	49500		
Exposures From Hand-to-Mouth Activity (Appendix C/Table 7)				
Day of application prior to watering in	613	355		
Day of application prior to watering in	1960	1134		

MOEs > 100 are not a concern to the Agency, Application rates considered are 7.5 and 12.5 pounds of active ingredient per acre. This table was developed based on the calculations presented in Appendix C/Tables 5 & 7 (actual monitoring data).

(6) Incident Reports

EPA obtained incident information concerning bensulide from three sources: the Office of Pesticide Programs (OPP) Incident Data System (IDS), the California Department of Food and Agriculture (CFDA; replaced by the Department of Pesticide Regulation in 1991), and the National Pesticide Telecommunications Network (NPTN; a toll-free information service supported by OPP). The IDS contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies, and individual consumers, submitted to OPP since 1992. The CFDA data consists of uniform reports, required by statute since 1982, from physicians on suspected pesticide poisonings and all illnesses suspected of being related to exposure to pesticides. The NPTN data consists of a tabulation of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991 into categories of human incidents, animals incidents, calls for information, and others. Bensulide was not included in the Data-Call-Ins issued by OPP in 1993 for 28 organophosphate and carbamate chemicals; therefore, no data were obtained from the Poison Control Centers on this chemical.

IDS Data

Two cases reported to the IDS involved individuals who were both exposed to bensulide in 1994 and experienced ocular irritation and pain. No further information on the dispositions of either of these two cases was reported.

CFDA Data

During the period from 1982 to 1995, 8 cases involving bensulide (6 of these involving exposure to bensulide alone) were reported. Two of these cases involved skin effects only, one dealt with eye effects only, and three were reported as systemic (not including skin or eye effects). Of the 6 persons exposed to bensulide alone, one person was reported as disabled (defined as taking time off from work) for more than 10 days, one person was disabled for an undefined period, and one person was hospitalized for 6-10 days. One of the 6 cases involved bensulide drift from non-target areas and one resulted from coincidental exposure. The remaining four cases were workrelated and involved one mixerloader and three applicators. The majority of these exposures were related to ground application of bensulide. Reported illnesses included symptoms of headaches, nausea, malaise, and nasal stuffiness. One of these six cases may have been changed from being regarded as pesticide-related to flu-related, but this could not be confirmed. Bensulide was ranked as 126th among pesticides as a cause of systemic poisoning in California.

NPTN Data

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusive, bensulide was ranked 145th, with 19 incidents in humans reported and 3 in animals (mostly pets).

Conclusions Based on Incident Reports

Very few illness cases have been reported due to bensulide, and none have been well confirmed. This conclusion supports the results of the risk assessment that has been completed for bensulide.

5. Aggregate Exposure

Aggregate exposure assessments for bensulide consist of dietary exposure (food and drinking water routes) and residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers who mouth grass). Aggregate exposure risk assessments are conducted for acute (1 day), short-term (1-7 days), intermediate (7-days to 3 months), and chronic (lifetime) exposure. For an acute aggregate exposure assessment, only dietary and drinking water exposure is considered. Occupational exposure is not presently considered in aggregate exposure assessments.

a. Acute Aggregate Exposure Assessment

An acute aggregate assessment consists of food and drinking water components, and does not include dermal and incidental oral exposure. Acute dietary exposure to bensulide was <1% of the acute RfD and was not of concern. Since drinking water monitoring data for bensulide were not available, drinking water levels of comparison (DWLOCs) were calculated and compared to estimated drinking water concentrations. As described in the Drinking Water section of this document, the DWLOC is the maximum concentration in drinking water which does not exceed a level of concern when considered together with dietary exposure. The drinking water estimated concentrations for surface and ground water were less than the acute DWLOCs, indicating that acute aggregate exposure to bensulide is not a concern (see the Drinking Water section of this document for more details).

b. Chronic Aggregate Exposure Assessment

Since there is no chronic residential exposure to bensulide, chronic aggregate assessment consisted only of dietary and drinking water exposure. Chronic dietary exposure was <1% of the chronic RfD and was not of concern. Since drinking water monitoring data for bensulide were not available, drinking water levels of comparison (DWLOCs) were calculated and compared to estimated drinking water concentrations. The chronic drinking water estimated concentration for surface water was greater than the chronic DWLOCs, indicating that chronic exposure to bensulide in drinking water may be of concern. When turf use was eliminated, the estimated surface water concentrations were comparable to the DWLOCs and are not of concern for adults, however concerns remained for infants and

children. However, the estimated concentrations for water from modeling are conservative and are higher than expected to be actually found in drinking water. The drinking water estimated concentration for ground water was less than the chronic DWLOCs and was not of concern. (See the Drinking Water section of this document for more details.)

c. Short-term Aggregate Exposure Assessment

The total margin of exposure (MOE) for combined dietary, dermal, and non-dietary oral exposures was calculated. The margin of exposure equals the NOAEL divided by the dose and should be 100 or greater for bensulide. Since both oral and dermal endpoints were used in calculating MOEs, the reciprocal equation, shown below was used in calculating the total MOE. Since there were no monitoring data for bensulide in water, an MOE for water could not be calculated and short-term drinking water levels of comparison were calculated in the next section of this document.

All endpoints were based on plasma cholinesterase inhibition. The endpoint for short-term dermal exposure was plasma cholinesterase inhibition from the 21-day dermal study (NOAEL = 50 mg/kg/day), the endpoint for short-term inhalation exposure was plasma cholinesterase inhibition in the rat developmental study (NOAEL = 5.5 mg/kg/day), and the endpoints for short-term dietary and non-dietary oral exposure were plasma cholinesterase inhibition in the acute neurotoxicity study.

Short-term aggregate exposures had total MOEs of greater than 100 and were not of concern, assuming that bensulide was watered in according to the label directions. If bensulide was not watered in, then total MOEs were less than 100, which exceeds a level of concern. Table 15 shows the short-term aggregate MOEs.

Table 15. Margins of Exposure for Short-Term Aggregate Exposure

	М	argin of Exp	osure (MOE =	: NOAEL/DOSE)
Population	Dermal Exposure	Inhalation Exposure	Dietary Exposure	Non-dietary Oral	Total MOE
Homeowners Who Apply (General Population Handlers)	187	9780	1,000,000	0	184
Yardwork (General Pop., Heavy Activity)	482	0	1,000,000	0	482
Golfers (General Pop., Light Activity)	8326	0	1,000,000	0	8,257
Toddlers	237	0	385,000	49,504	236

(1) Drinking Water Calculations for Short-term Aggregate Exposure

Drinking water was not included in calculations of short-term aggregate exposure because monitoring data for bensulide in drinking water were limited and could not be used. Instead, drinking water levels of comparison were calculated and compared to estimated drinking water concentrations from modeling. From the reciprocal equation, equation 1, below was used, and from the definition of MOE, equation 2, below was used. The drinking water level of comparison was calculated with equation 3.

- 2. Allowable Short Term Water Exposure = Short-term Dietary NOAEL
 Allowable MOE_{water}
- 3. DWLOC (ug/L) = Allowable Short Term Water Exposure (mg/kg/day) x Body Wt (kg)
 0.001 mg/μg x Drinking Water Consumption (L/day)

Drinking water levels of comparisons are shown in Table 16. The drinking water estimated concentrations for both ground and surface water were less than the drinking water levels of comparison and so there were no concerns for short-term aggregate exposure.

Table 16. Drinking Water Levels of Comparison for Short-term Aggregate Exposure

Population	Total MOE	Allowable Water MOE	Allowable Water Exposure	Ground Water (μg/L) ¹	Surface Water (µg/L)²	DWLOC (μg/L)
Homeowners Who Apply (General Population Handlers)	183	220	0.0682	0.9	158/947	2,388
Yardwork (General Pop., Heavy Activity)	482	126	0.1188	0.9	158/947	4,160
Golfers (General Pop., Light Activity)	8,257	101	0.1481	0.9	158/947	5,186
Toddlers	236	174	0.0836	0.9	158/947	130

¹From SCI-GROW modeling.

(2) Intermediate-term Aggregate Exposure Assessment

For handlers, a quantitative intermediate-term aggregate assessment was not conducted because intermediate-term homeowner handler exposures are not thought to occur. Additionally, it is Agency policy not to consider inhalation exposure in aggregate post-application scenarios and the same endpoint for dermal exposure was selected for both short-and intermediate-term exposures. Since turf transferrable residues declined over time, the short-term assessment represents the worst post-application risk because turf transferrable residues declined over time.

 $^{^2}$ Two values for surface water concentrations from PRZM-EXAMS modeling are reported. The value of 158 μ g/L is from vegetable application and the 947 μ g/L value is from turf use.

APPENDIX A BENSULIDE HANDLER EXPOSURE & RISK ASSESSMENT

		APPENDIX A/TABI	E 1: INPUT	PARAMETER	S FOR BENS	ULIDE HAND	LER EXPOSU	RE AND RISK	CALCULAT	TIONS			
			EXPOSURE	FACTORS				UNIT EX	(POSURES				
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET			ВА	SELINE	N	/IIN PPE	N	MAX PPE	EN	NG CONT	ROLS
		ORTARGET	RATE	ACRES OR	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal	Glove	Inhalation
				GALLONS	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	Use	(ug/lb ai)
				OCC	UPATIONAL	MIXER/LOAD	ERS					I	
1a	Mixing/loading Liquids for	AG - MIN	3	350	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
	Chemigation	AG - MIN	3	40	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
		AG - MAX	6	350	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
		AG - MAX	6	40	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
1b	Mixing/loading Liquids for	AG - MIN	3	80	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
	Groundboom Application	AG - MAX	6	80	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
		TURF/ORN - MIN	7.5	40	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
		TURF/ORN - MAX	12.5	40	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
1c	Mixing/loading Liquids for	TURF/ORN - MIN	7.5	50	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
	Professional Turf Application	TURF/ORN - MAX	12.5	50	2.9	1.2	0.023	0.12	0.017	0.12	0.0086	Yes	0.083
2	Loading Granulars for	TURF/ORN - MIN	7.5	40	0.0084	1.7	0.0069	0.17	0.0034	0.17	0.0002	No	0.034
	Tractor Drawn Spreader Application	TURF/ORN - MAX	12.5	40	0.0084	1.7	0.0069	0.17	0.0034	0.17	0.0002	No	0.034
				OC	CUPATIONAL	APPLICATO	RS						
3	Applying Sprays With a	AG - MIN	3	80	0.014	0.74	0.014	0.074	0.011	0.074	0.005	No	0.043
	Groundboom Sprayer	AG - MAX	6	80	0.014	0.74	0.014	0.074	0.011	0.074	0.005	No	0.043
		TURF/ORN - MIN	7.5	40	0.014	0.74	0.014	0.074	0.011	0.074	0.005	No	0.043
		TURF/ORN - MAX	12.5	40	0.014	0.74	0.014	0.074	0.011	0.074	0.005	No	0.043
4	Applying Granulars With a	TURF/ORN - MIN	7.5	40	0.01	1.2	0.0072	0.12	0.004	0.12	0.0021	No	0.22
	Tractor-Drawn Spreader	TURF/ORN - MAX	12.5	40	0.01	1.2	0.0072	0.12	0.004	0.12	0.0021	No	0.22
				OCCUPATION	ONAL MIXER/	LOADER/API	PLICATORS						
5	Low Pressure Handwand	TURF/ORN - MIN	7.5	5	100	30	0.43	3	0.37	3	NF	NF	NF
		TURF/ORN - MAX	12.5	5	100	30	0.43	3	0.37	3	NF	NF	NF
		TURF/ORN - MIN	7.5	7	100	30	0.43	3	0.37	3	NF	NF	NF
		TURF/ORN - MAX	12.5	7	100	30	0.43	3	0.37	3	NF	NF	NF
6	High Pressure Handwand	TURF/ORN/OCC	0.16	1000	No Data	120	2.5	12	1.6	12	NF	NF	NF
7	Backpack Sprayer	TURF/ORN - MIN	7.5	5	No Data	30	2.5	3	1.6	3	NF	NF	NF
		TURF/ORN - MAX	12.5	5	No Data	30	2.5	3	1.6	3	NF	NF	NF
		TURF/ORN - MIN	7.5	7	No Data	30	2.5	3	1.6	3	NF	NF	NF
		TURF/ORN - MAX	12.5	7	No Data	30	2.5	3	1.6	3	NF	NF	NF

			EXPOSURE	FACTORS				UNIT E	(POSURES				
SCEN.	SCEN. DESCRIPTOR	CROP TYPE			ВА	SELINE	N	/IN PPE	N	//AX PPE	EI	NG CONTI	ROLS
		OR TARGET	RATE		Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal	Glove	Inhalation
				GALLONS	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	(ug/lb ai)	(mg/lb ai)	Use	(ug/lb ai)
Note													
	TURF/ORN - MIN 7.5 7 3.7 2.6 0.36 0.26 0.21 0.26 NF NF NF TURF/ORN - MAX 12.5 7 3.7 2.6 0.36 0.26 0.21 0.26 NF NF NF												
	TURF/ORN - MIN 7.5 7 3.7 2.6 0.36 0.26 0.21 0.26 NF NF NF												
	TURF/ORN - MAX 12.5 7 3.7 2.6 0.36 0.26 0.21 0.26 NF NF NF												
9	Push-type Granular	TURF/ORN - MIN	7.5	5	2.9	6.3	1.27	0.63	0.7	0.63	NF	NF	NF
	Spreader	TURF/ORN - MAX	12.5	5	2.9	6.3	1.27	0.63	0.7	0.63	NF	NF	NF
10	Bellygrinder	TURF/ORN - MIN	7.5	5	10	62	9.3	6.2	5.7	6.2	NF	NF	NF
		TURF/ORN - MAX	12.5	5	10	62	9.3	6.2	5.7	6.2	NF	NF	NF
				HOMEOW	NER MIXER/L	OADER/APP	LICATORS						
9		TURF/ORN - MIN	7.5	0.5	3	6.3	NF	NF	NF	NF	NF	NF	NF
	Spreader	TURF/ORN - MAX	12.5	0.5	3	6.3	NF	NF	NF	NF	NF	NF	NF
10	Bellygrinder	TURF/ORN - MIN	7.5	0.5	110	62	NF	NF	NF	NF	NF	NF	NF
		TURF/ORN - MAX	12.5	0.5	110	62	NF	NF	NF	NF	NF	NF	NF
			Dermal Min P	PE = Minimum	n PPE or basel	ine clothing w	ith chemical-re	sistant gloves					
		Dermal Max PPE	= Maximum F	PPE or baselin	e clothing with	an additional I	ayer of clothing	and chemical	resistant glo	oves			

	API	PENDIX A/TABLE 2:	BENSULIDE HA	NDLER EXPO	SURE AND RIS	SK CALCULATI	ONS AT THE E	BASELINE PR	OTECTION LEVEL		
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	POSURE	DAILY	DOSE	DERMAL	INHAL	ATION MOEs	COMI	BINED MOEs
SCEN.		OR TARGET	DERMAL	INHALAT.	DERMAL	INHALAT.	MOEs	SHORT	INTERMEDIATE	SHORT	INTERMEDIATE
			(mg/day)	(mg/day)	(mg/kg/day)	(mg/kg/day)		TERM	TERM	TERM	TERM
				OCCU	PATIONAL MIX	ER/LOADERS					
1a	Mixing/loading Liquids for	AG - MIN	3045.0000	1.2600	43.5000	0.0180	1.1	305.6	27.8	1.1	1.1
	Chemigation	AG - MIN	348.0000	0.1440	4.9714	0.0021	10.1	2673.6	243.1	10.0	9.7
		AG - MAX	6090.0000	2.5200	87.0000	0.0360	0.6	152.8	13.9	0.6	0.6
		AG - MAX	696.0000	0.2880	9.9429	0.0041	5.0	1336.8	121.5	5.0	4.8
1b	Mixing/loading Liquids for	AG - MIN	696.0000	0.2880	9.9429	0.0041	5.0	1336.8	121.5	5.0	4.8
	Groundboom Application	AG - MAX	1392.0000	0.5760	19.8857	0.0082	2.5	668.4	60.8	2.5	2.4
		TURF/ORN - MIN	870.0000	0.3600	12.4286	0.0051	4.0	1069.4	97.2	4.0	3.9
		TURF/ORN - MAX	1450.0000	0.6000	20.7143	0.0086	2.4	641.7	58.3	2.4	2.3
1c	Mixing/loading Liquids for	TURF/ORN - MIN	1087.5000	0.4500	15.5357	0.0064	3.2	855.6	77.8	3.2	3.1
	Professional Turf Application	TURF/ORN - MAX	1812.5000	0.7500	25.8929	0.0107	1.9	513.3	46.7	1.9	1.9
2	Loading Granulars for	TURF/ORN - MIN	2.5200	0.5100	0.0360	0.0073	1388.9	754.9	68.6	489.1	65.4
	Tractor Drawn Spreader Application	TURF/ORN - MAX	4.2000	0.8500	0.0600	0.0121	833.3	452.9	41.2	293.4	39.2
				OCCL	JPATIONAL AP	PLICATORS					
3	Applying Sprays With a	AG - MIN	3.3600	0.1776	0.0480	0.0025	1041.7	2167.8	197.1	703.6	165.7
	Groundboom Sprayer	AG - MAX	6.7200	0.3552	0.0960	0.0051	520.8	1083.9	98.5	351.8	82.9
		TURF/ORN - MIN	4.2000	0.2220	0.0600	0.0032	833.3	1734.2	157.7	562.9	132.6
		TURF/ORN - MAX	7.0000	0.3700	0.1000	0.0053	500.0	1040.5	94.6	337.7	79.5
4	Applying Granulars With a	TURF/ORN - MIN	3.0000	0.3600	0.0429	0.0051	1166.7	1069.4	97.2	558.0	89.7
	Tractor-Drawn Spreader	TURF/ORN - MAX	5.0000	0.6000	0.0714	0.0086	700.0	641.7	58.3	334.8	53.8
				OCCUPATION	IAL MIXER/LOA	ADER/APPLICA	TORS				
5	Low Pressure Handwand	TURF/ORN - MIN	3750.0000	1.1250	53.5714	0.0161	0.9	342.2	31.1	0.9	0.9
		TURF/ORN - MAX	6250.0000	1.8750	89.2857	0.0268	0.6	205.3	18.7	0.6	0.5
		TURF/ORN - MIN	5250.0000	1.5750	75.0000	0.0225	0.7	244.4	22.2	0.7	0.6
		TURF/ORN - MAX	8750.0000	2.6250	125.0000	0.0375	0.4	146.7	13.3	0.4	0.4
6	High Pressure Handwand	TURF/ORN/OCC	No Data	19.2000	No Data	0.2743	No Data	20.1	1.8	No Data	No Data

	API	PENDIX A/TABLE 2:	BENSULIDE HA	NDLER EXPO	SURE AND RIS	SK CALCULATI	ONS AT THE B	ASELINE PR	OTECTION LEVEL		
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EXI	POSURE	DAILY	DOSE	DERMAL	INHALA	ATION MOEs	COME	BINED MOEs
SCEN.		OR TARGET	DERMAL	INHALAT.	DERMAL	INHALAT.	MOEs	SHORT	INTERMEDIATE	SHORT	INTERMEDIATE
			(mg/day)	(mg/day)	(mg/kg/day)	(mg/kg/day)		TERM	TERM	TERM	TERM
7	Backpack Sprayer	TURF/ORN - MIN	No Data	1.1250	No Data	0.0161	No Data	342.2	31.1	No Data	No Data
		TURF/ORN - MAX	No Data	1.8750	No Data	0.0268	No Data	205.3	18.7	No Data	No Data
		TURF/ORN - MIN	No Data	1.5750	No Data	0.0225	No Data	244.4	22.2	No Data	No Data
		TURF/ORN - MAX	No Data	2.6250	No Data	0.0375	No Data	146.7	13.3	No Data	No Data
8	Low Pressure/High volume	TURF/ORN - MIN	138.7500	0.0975	1.9821	0.0014	25.2	3948.7	359.0	25.1	23.6
	Turfgun	TURF/ORN - MAX	231.2500	0.1625	3.3036	0.0023	15.1	2369.2	215.4	15.0	14.1
		TURF/ORN - MIN	194.2500	0.1365	2.7750	0.0020	18.0	2820.5	256.4	17.9	16.8
		TURF/ORN - MAX	323.7500	0.2275	4.6250	0.0033	10.8	1692.3	153.8	10.7	10.1
9	Push-type Granular	TURF/ORN - MIN	108.7500	0.2363	1.5536	0.0034	32.2	1629.6	148.1	31.6	26.4
	Spreader	TURF/ORN - MAX	181.2500	0.3938	2.5893	0.0056	19.3	977.8	88.9	18.9	15.9
10	Bellygrinder	TURF/ORN - MIN	375.0000	2.3250	5.3571	0.0332	9.3	165.6	15.1	8.8	5.8
		TURF/ORN - MAX	625.0000	3.8750	8.9286	0.0554	5.6	99.4	9.0	5.3	3.5
				HOMEOWNE	R MIXER/LOAI	DER/APPLICAT	TORS				
9	Push-type Granular	TURF/ORN - MIN	11.2500	0.0236	0.1607	0.0003	311.1	16296.3	N/A	305.3	N/A
	Spreader	TURF/ORN - MAX	18.7500	0.0394	0.2679	0.0006	186.7	9777.8	N/A	183.2	N/A
10	Bellygrinder	TURF/ORN - MIN	412.5000	0.2325	5.8929	0.0033	8.5	1655.9	N/A	8.4	N/A
		TURF/ORN - MAX	687.5000	0.3875	9.8214	0.0055	5.1	993.5	N/A	5.1	N/A

	APPENDIX A/T	ABLE 3: BENSULID	E HANDLER EX	(POSURE AND	RISK CALCUI	LATIONS AT N	AINIMUM PPE	PROTECTION	LEVELS (Gloves &	Respirators)	
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EXI	POSURE	DAILY	DOSE	DERMAL	INHALA	TION MOEs	COME	BINED MOEs
SCEN.		OR TARGET	DERMAL (mg/day)	INHALAT. (mg/day)	DERMAL (mg/kg/day)	INHALAT. (mg/kg/day)	MOEs	SHORT TERM	INTERMEDIATE TERM	SHORT TERM	INTERMEDIATE TERM
				OCCL	JPATIONAL MI	XER/LOADER	S				
1a	Mixing/loading Liquids for	AG - MIN	24.1500	0.1260	0.3450	0.0018	144.9	3055.6	277.8	138.4	95.2
	Chemigation	AG - MIN	2.7600	0.0144	0.0394	0.0002	1268.1	26736.1	2430.6	1210.7	833.3
		AG - MAX	48.3000	0.2520	0.6900	0.0036	72.5	1527.8	138.9	69.2	47.6
		AG - MAX	5.5200	0.0288	0.0789	0.0004	634.1	13368.1	1215.3	605.3	416.7
1b	Mixing/loading Liquids for	AG - MIN	5.5200	0.0288	0.0789	0.0004	634.1	13368.1	1215.3	605.3	416.7
	Groundboom Application	AG - MAX	11.0400	0.0576	0.1577	0.0008	317.0	6684.0	607.6	302.7	208.3
		TURF/ORN - MIN	6.9000	0.0360	0.0986	0.0005	507.2	10694.4	972.2	484.3	333.3
		TURF/ORN - MAX	11.5000	0.0600	0.1643	0.0009	304.3	6416.7	583.3	290.6	200.0
1c	Mixing/loading Liquids for	TURF/ORN - MIN	8.6250	0.0450	0.1232	0.0006	405.8	8555.6	777.8	387.4	266.7
	Professional Turf Application	TURF/ORN - MAX	14.3750	0.0750	0.2054	0.0011	243.5	5133.3	466.7	232.5	160.0
2	3	TURF/ORN - MIN	2.0700	0.0510	0.0296	0.0007	1690.8	7549.0	686.3	1381.4	488.1
	Drawn Spreader Application	TURF/ORN - MAX	3.4500	0.0850	0.0493	0.0012	1014.5	4529.4	411.8	828.8	292.9
				OCC	UPATIONAL A	PPLICATORS	<u> </u>				
3	Applying Sprays With a	AG - MIN	3.3600	0.0178	0.0480	0.0003	1041.7	21677.9	1970.7	993.9	681.5
	Groundboom Sprayer	AG - MAX	6.7200	0.0355	0.0960	0.0005	520.8	10839.0	985.4	497.0	340.7
		TURF/ORN - MIN	4.2000	0.0222	0.0600	0.0003	833.3	17342.3	1576.6	795.1	545.2
		TURF/ORN - MAX	7.0000	0.0370	0.1000	0.0005	500.0	10405.4	945.9	477.1	327.1
4	Applying Granulars With a	TURF/ORN - MIN	2.1600	0.0360	0.0309	0.0005	1620.4	10694.4	972.2	1407.2	607.6
	Tractor-Drawn Spreader	TURF/ORN - MAX	3.6000	0.0600	0.0514	0.0009	972.2	6416.7	583.3	844.3	364.6
				OCCUPATIO	NAL MIXER/LC	ADER/APPLI	CATORS				
5	Low Pressure Handwand	TURF/ORN - MIN	16.1250	0.1125	0.2304	0.0016	217.1	3422.2	311.1	204.1	127.9
		TURF/ORN - MAX	26.8750	0.1875	0.3839	0.0027	130.2	2053.3	186.7	122.5	76.7
		TURF/ORN - MIN	22.5750	0.1575	0.3225	0.0023	155.0	2444.4	222.2	145.8	91.3
		TURF/ORN - MAX	37.6250	0.2625	0.5375	0.0038	93.0	1466.7	133.3	87.5	54.8
6	High Pressure Handwand	TURF/ORN/OCC	400.0000	1.9200	5.7143	0.0274	8.8	200.5	18.2	8.4	5.9

	APPENDIX A/T	ABLE 3: BENSULID	E HANDLER EX	(POSURE AND	RISK CALCU	LATIONS AT N	/INIMUM PPE	PROTECTION	LEVELS (Gloves &	Respirators)	
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	POSURE	DAILY	DOSE	DERMAL	INHALA [*]	TION MOEs	COME	BINED MOEs
SCEN.		OR TARGET	DERMAL (mg/day)	INHALAT. (mg/day)	DERMAL (mg/kg/day)	INHALAT. (mg/kg/day)	MOEs	SHORT TERM	INTERMEDIATE TERM	SHORT TERM	INTERMEDIATE TERM
7	Backpack Sprayer	TURF/ORN - MIN	93.7500	0.1125	1.3393	0.0016	37.3	3422.2	311.1	36.9	33.3
		TURF/ORN - MAX	156.2500	0.1875	2.2321	0.0027	22.4	2053.3	186.7	22.2	20.0
		TURF/ORN - MIN	131.2500	0.1575	1.8750	0.0023	26.7	2444.4	222.2	26.4	23.8
		TURF/ORN - MAX	218.7500	0.2625	3.1250	0.0038	16.0	1466.7	133.3	15.8	14.3
8	Low Pressure/High volume	TURF/ORN - MIN	13.5000	0.0098	0.1929	0.0001	259.3	39487.2	3589.7	257.6	241.8
	Turfgun	TURF/ORN - MAX	22.5000	0.0163	0.3214	0.0002	155.6	23692.3	2153.8	154.5	145.1
		TURF/ORN - MIN	18.9000	0.0137	0.2700	0.0002	185.2	28205.1	2564.1	184.0	172.7
		TURF/ORN - MAX	31.5000	0.0228	0.4500	0.0003	111.1	16923.1	1538.5	110.4	103.6
9	Push-type Granular Spreader	TURF/ORN - MIN	47.6250	0.0236	0.6804	0.0003	73.5	16296.3	1481.5	73.2	70.0
		TURF/ORN - MAX	79.3750	0.0394	1.1339	0.0006	44.1	9777.8	888.9	43.9	42.0
10	Bellygrinder	TURF/ORN - MIN	348.7500	0.2325	4.9821	0.0033	10.0	1655.9	150.5	10.0	9.4
		TURF/ORN - MAX	581.2500	0.3875	8.3036	0.0055	6.0	993.5	90.3	6.0	5.6
				HOMEOWN	ER MIXER/LOA	ADER/APPLIC	ATORS				
9	Push-type Granular Spreader	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
10	Bellygrinder	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F

	I	APPENDIX A/TABLE	4: BENSULIDE	HANDLER EXP	OSURE AND R	ISK CALCULA	TIONS AT MAX	IMUM PPE PR	OTECTION LEVELS		
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	POSURE	DAILY I	DOSE	DERMAL	INHAL	ATION MOEs	CON	MBINED MOEs
SCEN.		OR TARGET	DERMAL (mg/day)	INHALAT. (mg/day)	DERMAL (mg/kg/day)	INHALAT. (mg/kg/day)	MOEs	SHORT TERM	INTERMEDIATE TERM	SHORT TERM	INTERMEDIATE TERM
				OCC	CUPATIONAL M	IXER/LOADER	S				
1a	Mixing/loading Liquids for	AG - MIN	17.8500	0.1260	0.2550	0.0018	196.1	3055.6	277.8	184.3	114.9
	Chemigation	AG - MIN	2.0400	0.0144	0.0291	0.0002	1715.7	26736.1	2430.6	1612.2	1005.7
		AG - MAX	35.7000	0.2520	0.5100	0.0036	98.0	1527.8	138.9	92.1	57.5
		AG - MAX	4.0800	0.0288	0.0583	0.0004	857.8	13368.1	1215.3	806.1	502.9
1b	Mixing/loading Liquids for	AG - MIN	4.0800	0.0288	0.0583	0.0004	857.8	13368.1	1215.3	806.1	502.9
	Groundboom Application	AG - MAX	8.1600	0.0576	0.1166	0.0008	428.9	6684.0	607.6	403.1	251.4
		TURF/ORN - MIN	5.1000	0.0360	0.0729	0.0005	686.3	10694.4	972.2	644.9	402.3
		TURF/ORN - MAX	8.5000	0.0600	0.1214	0.0009	411.8	6416.7	583.3	386.9	241.4
1c	Mixing/loading Liquids for Professional Turf	TURF/ORN - MIN	6.3750	0.0450	0.0911	0.0006	549.0	8555.6	777.8	515.9	321.8
	Application	TURF/ORN - MAX	10.6250	0.0750	0.1518	0.0011	329.4	5133.3	466.7	309.5	193.1
2	Loading Granulars for	TURF/ORN - MIN	1.0200	0.0510	0.0146	0.0007	3431.4	7549.0	686.3	2359.1	1571.9
	Tractor Drawn Spreader Application	TURF/ORN - MAX	1.7000	0.0850	0.0243	0.0012	2058.8	4529.4	411.8	1415.4	343.1
	_			OC	CUPATIONAL A	APPLICATORS	3				
3	Applying Sprays With a	AG - MIN	2.6400	0.0178	0.0377	0.0003	1325.8	21677.9	1970.7	1249.4	792.6
	Groundboom Sprayer	AG - MAX	5.2800	0.0355	0.0754	0.0005	662.9	10839.0	985.4	624.7	396.3
		TURF/ORN - MIN	3.3000	0.0222	0.0471	0.0003	1060.6	17342.3	1576.6	999.5	634.1
		TURF/ORN - MAX	5.5000	0.0370	0.0786	0.0005	636.4	10405.4	945.9	599.7	380.4
4	Applying Granulars With	TURF/ORN - MIN	1.2000	0.0360	0.0171	0.0005	2916.7	10694.4	972.2	2291.7	729.2
	a Tractor-Drawn Spreader	TURF/ORN - MAX	2.0000	0.0600	0.0286	0.0009	1750.0	6416.7	583.3	1375.0	437.5
				OCCUPATION	ONAL MIXER/LO	DADER/APPLI	CATORS				
5	Low Pressure Handwand	TURF/ORN - MIN	13.8750	0.1125	0.1982	0.0016	252.3	3422.2	311.1	234.9	139.3
		TURF/ORN - MAX	23.1250	0.1875	0.3304	0.0027	151.4	2053.3	186.7	141.0	83.6
		TURF/ORN - MIN	19.4250	0.1575	0.2775	0.0023	180.2	2444.4	222.2	167.8	99.5
		TURF/ORN - MAX	32.3750	0.2625	0.4625	0.0038	108.1	1466.7	133.3	100.7	59.7
6	High Pressure Handwand	TURF/ORN/OCC	256.0000	1.9200	3.6571	0.0274	13.7	200.5	18.2	12.8	7.8

		APPENDIX A/TABLE 4	4: BENSULIDE	HANDLER EXP	OSURE AND R	ISK CALCULA	TIONS AT MAX	IMUM PPE PR	OTECTION LEVELS		
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	POSURE	DAILY	DOSE	DERMAL	INHAL	ATION MOEs	CON	MBINED MOEs
SCEN.		OR TARGET	DERMAL (mg/day)	INHALAT. (mg/day)	DERMAL (mg/kg/day)	INHALAT. (mg/kg/day)	MOEs	SHORT TERM	INTERMEDIATE TERM	SHORT TERM	INTERMEDIATE TERM
7	Backpack Sprayer	TURF/ORN - MIN	60.0000	0.1125	0.8571	0.0016	58.3	3422.2	311.1	57.4	49.1
		TURF/ORN - MAX	100.0000	0.1875	1.4286	0.0027	35.0	2053.3	186.7	34.4	29.5
		TURF/ORN - MIN	84.0000	0.1575	1.2000	0.0023	41.7	2444.4	222.2	41.0	35.1
		TURF/ORN - MAX	140.0000	0.2625	2.0000	0.0038	25.0	1466.7	133.3	24.6	21.1
8	Low Pressure/High	TURF/ORN - MIN	7.8750	0.0098	0.1125	0.0001	444.4	39487.2	3589.7	439.5	395.5
	volume Turfgun	TURF/ORN - MAX	13.1250	0.0163	0.1875	0.0002	266.7	23692.3	2153.8	263.7	237.3
		TURF/ORN - MIN	11.0250	0.0137	0.1575	0.0002	317.5	28205.1	2564.1	313.9	282.5
		TURF/ORN - MAX	18.3750	0.0228	0.2625	0.0003	190.5	16923.1	1538.5	188.4	169.5
9	Push-type Granular	TURF/ORN - MIN	26.2500	0.0236	0.3750	0.0003	133.3	16296.3	1481.5	132.3	122.3
	Spreader	TURF/ORN - MAX	43.7500	0.0394	0.6250	0.0006	80.0	9777.8	888.9	79.4	73.4
10	Bellygrinder	TURF/ORN - MIN	213.7500	0.2325	3.0536	0.0033	16.4	1655.9	150.5	16.2	14.8
		TURF/ORN - MAX	356.2500	0.3875	5.0893	0.0055	9.8	993.5	90.3	9.7	8.9
				HOMEOW	NER MIXER/LO	ADER/APPLIC	ATORS				
9	Push-type Granular	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
	Spreader	TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
10	Bellygrinder	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F

	APPEN	DIX A/TABLE 5: BEN	SULIDE HAN	DLER EXPOSU	JRE AND RISK	CALCULATIO	NS AT ENGIN	EERING CONTI	ROL PROTECTION	LEVELS	
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	(POSURE	DAILY	DOSE	DERMAL	INHALA ⁻	TION MOEs	COMB	NED MOEs
SCEN.		OR TARGET	DERMAL (mg/day)	INHALAT. (mg/day)	DERMAL (mg/kg/day)	INHALAT. (mg/kg/day)	MOEs	SHORT TERM	INTERMEDIATE TERM	SHORT TERM	INTERMEDIATE TERM
			, , , , , ,	OC	CUPATIONAL	MIXER/LOADE	RS				
1a	Mixing/loading Liquids for	AG - MIN	9.0300	0.0872	0.1290	0.0012	387.6	4417.7	401.6	356.3	197.2
	Chemigation	AG - MIN	1.0320	0.0100	0.0147	0.0001	3391.5	38654.6	3514.1	3117.9	1725.8
		AG - MAX	18.0600	0.1743	0.2580	0.0025	193.8	2208.8	200.8	178.2	98.6
		AG - MAX	2.0640	0.0199	0.0295	0.0003	1695.7	19327.3	1757.0	1559.0	862.9
1b	Mixing/loading Liquids for	AG - MIN	2.0640	0.0199	0.0295	0.0003	1695.7	19327.3	1757.0	1559.0	862.9
	Groundboom Application	AG - MAX	4.1280	0.0398	0.0590	0.0006	847.9	9663.7	878.5	779.5	431.5
		TURF/ORN - MIN	2.5800	0.0249	0.0369	0.0004	1356.6	15461.8	1405.6	1247.2	690.3
		TURF/ORN - MAX	4.3000	0.0415	0.0614	0.0006	814.0	9277.1	843.4	748.3	414.2
1c	Mixing/loading Liquids for	TURF/ORN - MIN	3.2250	0.0311	0.0461	0.0004	1085.3	12369.5	1124.5	997.7	552.3
	Professional Turf Application	TURF/ORN - MAX	5.3750	0.0519	0.0768	0.0007	651.2	7421.7	674.7	598.6	331.4
2	Loading Granulars for	TURF/ORN - MIN	0.0504	0.0102	0.0007	0.0001	69444.4	37745.1	3431.4	24453.8	3269.8
	Tractor Drawn Spreader Application	TURF/ORN - MAX	0.0840	0.0170	0.0012	0.0002	41666.7	22647.1	2058.8	14672.3	1961.9
				0	CCUPATIONA	L APPLICATOR	RS				
3	Applying Sprays With a	AG - MIN	1.2000	0.0103	0.0171	0.0001	2916.7	37306.2	3391.5	2705.2	1568.1
	Groundboom Sprayer	AG - MAX	2.4000	0.0206	0.0343	0.0003	1458.3	18653.1	1695.7	1352.6	784.1
		TURF/ORN - MIN	1.5000	0.0129	0.0214	0.0002	2333.3	29845.0	2713.2	2164.1	1254.5
		TURF/ORN - MAX	2.5000	0.0215	0.0357	0.0003	1400.0	17907.0	1627.9	1298.5	752.7
4	Applying Granulars With a	TURF/ORN - MIN	0.6300	0.0660	0.0090	0.0009	5555.6	5833.3	530.3	2845.5	484.1
	Tractor-Drawn Spreader	TURF/ORN - MAX	1.0500	0.1100	0.0150	0.0016	3333.3	3500.0	318.2	1707.3	290.5
				OCCUPAT	IONAL MIXER	LOADER/APPI	LICATORS				
5	Low Pressure Handwand	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
6	High Pressure Handwand	TURF/ORN/OCC	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
7	Backpack Sprayer	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
8	Low Pressure/High volume	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
	Turfgun	TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
9	Push-type Granular	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
	Spreader	TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
10	Bellygrinder	TURF/ORN - MIN	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F

	APPEN	IDIX A/TABLE 5: BEN	SULIDE HAN	DLER EXPOSI	JRE AND RISK	CALCULATION	NS AT ENGIN	EERING CONTI	ROL PROTECTION	LEVELS		
	SCEN. DESCRIPTOR	CROP TYPE	DAILY EX	XPOSURE	DAILY	DOSE	DERMAL	INHALA ⁻	TION MOEs	COMBI	NED MOEs	
SCEN.	(mg/day) (mg/day) (mg/kg/day) TERM TERM TERM TERM											
	HOMEOWNER MIXER/LOADER/APPLICATORS											
9	HOMEOWNER MIXER/LOADER/APPLICATORS Push-type Granular TURF/ORN - MIN N/F N/F N/F N/F N/F N/F N/F N/F N/F											
	Spreader	TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	
10	10 Bellygrinder TURF/ORN - MIN N/F N/F N/F N/F N/F N/F N/F N/F N/F N/											
		TURF/ORN - MAX	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	N/F	

		Appendix A/Table 6: Exp	posure Scenario Descriptions for the Use of Bensulide
Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
			Mixer/Loader Descriptors
Mixing/Loading Liquid Formulations (1a/1b/1c)	PHED V1.1	350 acres for aerial, 80 acres for groundboom in agriculture, 40 acres for groundboom on golf course turf, and 10 professional applicators/day each treating 5 acres/day for the turf loading scenarios	Baseline: All exposure data are high confidence. No protection factors were needed to define the unit exposure values. PPE: As appropriate, the same dermal and inhalation data were used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 90% protection factor to account for the use of a respirator. High confidence in all data. Hand exposure data with gloves were monitored. Engineering Controls: All exposure data are high confidence. Gloves were worn during the use of the engineering controls. No protection factors were needed to define the unit exposure values.
Loading Granular Formulations (2)	PHED V1.1	80 acres for tractor drawn spreaders for most crops; 40 acres for golf course turf	 Baseline: Low confidence in dermal and hand data (due to low hand replicates). High confidence in inhalation data. No protection factors were needed to define the unit exposure values. PPE: Monitoring data for each dermal scenario were available. For the single layer clothing with gloves scenario, the same dermal and inhalation data were used as for the baseline with hand exposure data that were monitored with gloves (considered medium confidence due to poordata quality). For the double layer clothing with gloves scenario, monitoring data were available (considered low confidence based on insufficient data). A 90 percent protection factor was applied to account for the use of a respirator. Engineering Controls: A 98 percent protection factor was applied to the baseline data to account for the use of an engineering control (e.g., closed loading system).
			Applicator Descriptors
Applying Sprays with a Groundboom Sprayer (3)	PHED V1.1	80 acres in agricultural settings and 40 acres on golf course turf	Baseline: High confidence in hand, dermal, and inhalation data. No protection factors were needed to define the unit exposure values. PPE: As appropriate, the same dermal and inhalation data were used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 90% protection factor to account for the use of a respirator. High confidence in dermal and inhalation data. Hand exposure data with gloves were monitored (considered medium confidence). Engineering Controls: Medium confidence in hand and dermal data. High confidence in inhalation data. No protection factors were needed to define the unit exposure values.
Applying Granulars with a Tractor Drawn Spreader (4)	PHED V1.1	40 acres for golf course turf	Baseline: Low confidence in hand, dermal, and inhalation data. No protection factors were required to define the unit exposure values. PPE: As appropriate, the same dermal, hand, and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing, a 90% protection factor to account for the use of chemical resistant gloves, and a 90% protection factor to account for the use of a respirator. Engineering Controls: High confidence in hand, dermal, and inhalation data. No protection factors were required to define the unit exposure values er/Loader/Applicator Descriptors

		Appendix A/Table 6: Exp	posure Scenario Descriptions for the Use of Bensulide				
Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b				
			Baseline: Low confidence in hand and dermal data. Inhalation data are medium confidence. No protection factors were required to define the unit exposure values.				
Mixing/Loading/Applying with a Low Pressure Handwand (5)	PHED V1.1	5 acres for occupational uses	PPE: As appropriate, the same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 90% protection factor to account for the use of a respirator. Low confidence in dermal data. Hand exposure data with gloves were monitored (considered low confidence). Medium confidence in inhalation monitoring data.				
			Engineering Controls: Not feasible				
			Baseline: Only low confidence inhalation data available (no non-gloved hand monitoring data are available, therefore the assessment was not completed).				
Mixing/Loading/Applying with a High Pressure Handwand (6)	PHED V1.1	1,000 gallons	PPE: Low confidence single layer clothing dermal monitoring data available, coupled with a 50% protection factor account for an additional layer of clothing. Inhalation data coupled with a 90% protection factor to account for the use of a respirator. Hand exposure data with gloves were monitored (considered low confidence).				
			Engineering Controls: Not feasible				
			Baseline: Only low confidence inhalation data available (no non-gloved hand monitoring data are available, therefore the assessment was not completed).				
Mixing/Loading/Applying with a Backpack Sprayer (7)	PHED V1.1	5 acres for occupational uses	PPE: Low confidence single layer clothing dermal monitoring data available, coupled with a 50% protection factor to account for an additional layer of clothing. Inhalation data coupled with a 90% protection factor to account for the use of a respirator. Hand exposure data with gloves were monitored (considered low confidence).				
			Engineering Controls: Not feasible				
			Data for open mixing of liquids and handgun turfgrass application were combined to generate mixer/loader/applicator value as this is the most likely exposure scenario.				
			For mixer/loader criteria: see PHED data for open mixing/loading liquids (Exp. Scenario 1)				
Mixing/Loading/Applying with a Handgun (turf grass application) (8)	PHED V1.1	5 acres for occupational uses.	Baseline for application: Low confidence in hand, dermal, and inhalation data. Baseline dataset was based on the use of chemical-resistant gloves. Therefore, a reverse 90% PF was used on the gloved hand data to assess baseline exposure for individuals wearing no gloves (i.e., it is a typical use scenario demanding a baseline assessment and the exposures are generally lower compared with other handheld methods).				
			PPE for applicator: As appropriate, the same dermal, hand, and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 90% protection factor to account for the use of a respirator. Hand exposure data with gloves were monitored (considered low confidence).				
			Engineering Controls: Not feasible.				

		Appendix A/Table 6: Exp	osure Scenario Descriptions for the Use of Bensulide
Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
Mixing/Loading/Applying with a Push-Type Granular Spreader (9)	PHED V1.1	0.5 acre for homeowners 5 acres for occupational uses.	 Baseline: Low confidence in the dermal and hand data. High confidence in the inhalation data. No protection factors were required to define the unit exposure values (a 50 percent protection factor was used to back calculate the homeowner exposure scenario). PPE: As appropriate, the same dermal, hand, and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing, a 90% protection factor to account for the use of chemical resistant gloves, and a 90% protection factor to account for the use of a respirator. Engineering Controls: Not feasible.
Mixing/Loading/Applying with a Bellygrinder (10)	PHED V1.1	0.5 acre for homeowners 5 acres for occupational uses.	Baseline: Medium confidence in hand and dermal data. High confidence in inhalation data. No protection factors were required to define the unit exposure values (also applies to homeowner scenarios). PPE: As appropriate, the same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 90% protection factor to account for the use of a respirator. Hand exposure data with gloves were monitored (considered low confidence). Engineering Controls: Not feasible.

^aAll Standard Assumptions are based on a typical work day (the components that involve pesticide use) as estimated by HED.

High = grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates.

Protection factors applied to exposure data for the use of respiratory protection, protection afforded with the use of an additional layer of clothing, and protection from the use of chemical resistant gloves are as follows: 90 % (respirator); 50 % (layer of clothing); and 90% (gloves).

bAll handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. Generic data confidence categories are assigned as follows:

		APPENDIX A	TABLE 7: BEI	NSULIDE MOEs	ATTRIBUTABLE TO	DERMAL EXPOSURE		
			EXPOSUR	E FACTORS		DERMAL MOEs FOR VARYI	NG LEVELS OF PROTECT	TON
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	RATE	ACRES OR GALLONS	BASELINE	MINIMUM PPE (SINGLE LAYER & GLOVES)	MAXIMUM PPE (DOUBLE LAYER & GLOVES)	ENG. CONTROLS
			00	CCUPATIONAL N	/IXER/LOADERS			
		AG - MIN	3	350	1.1	144.9	196.1	387.6
1a	Mixing/loading Liquids for	AG - MIN	3	40	10.1	1268.1	1715.7	3391.5
la	Chemigation	AG - MAX	6	350	0.6	72.5	98.0	193.8
		AG - MAX	6	40	5.0	634.1	857.8	1695.7
		AG - MIN	3	80	5.0	634.1	857.8	1695.7
1 h	Mixing/loading Liquids for	AG - MAX	6	80	2.5	317.0	428.9	847.9
1b	Groundboom Application	TURF/ORN - MIN	7.5	40	4.0	507.2	686.3	1356.6
		TURF/ORN - MAX	12.5	40	2.4	304.3	411.8	814.0
4-	1c Mixing/loading Liquids for Professional Turf Application	TURF/ORN - MIN	7.5	50	3.2	405.8	549.0	1085.3
10		TURF/ORN - MAX	12.5	50	1.9	243.5	329.4	651.2
2	Loading Granulars for Tractor	TURF/ORN - MIN	7.5	40	1388.9	1690.8	3431.4	69444.4
2	Drawn Spreader Application	TURF/ORN - MAX	12.5	40	833.3	1014.5	2058.8	41666.7
			C	OCCUPATIONAL	APPLICATORS			
		AG - MIN	3	80	1041.7	1041.7	1325.8	2916.7
3	Applying Sprays With a	AG - MAX	6	80	520.8	520.8	662.9	1458.3
3	Groundboom Sprayer	TURF/ORN - MIN	7.5	40	833.3	833.3	1060.6	2333.3
		TURF/ORN - MAX	12.5	40	500.0	500.0	636.4	1400.0
	Applying Granulars With a	TURF/ORN - MIN	7.5	40	1166.7	1620.4	2916.7	5555.6
4	Tractor-Drawn Spreader	TURF/ORN - MAX	12.5	40	700.0	972.2	1750.0	3333.3
			OCCUPA	TIONAL MIXER/L	OADER/APPLICAT	ORS		
		TURF/ORN - MIN	7.5	5	0.9	217.1	252.3	N/F
5	Low Pressure Handwand	TURF/ORN - MAX	12.5	5	0.6	130.2	151.4	N/F
5	LOW FIESSUIE HAIIUWAIID	TURF/ORN - MIN	7.5	7	0.7	155.0	180.2	N/F
		TURF/ORN - MAX	12.5	7	0.4	93.0	108.1	N/F
6	High Pressure Handwand	TURF/ORN/OCC	0.16	1000	No Data	8.8	13.7	N/F

		APPENDIX A	TABLE 7: BEI	NSULIDE MOEs	ATTRIBUTABLE TO	DERMAL EXPOSURE			
			EXPOSUR	E FACTORS	DERMAL MOEs FOR VARYING LEVELS OF PROTECTION				
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	RATE	ACRES OR GALLONS	BASELINE	MINIMUM PPE (SINGLE LAYER & GLOVES)	MAXIMUM PPE (DOUBLE LAYER & GLOVES)	ENG. CONTROLS	
		TURF/ORN - MIN	7.5	5	No Data	37.3	58.3	N/F	
7	Doolsnools Chrossor	TURF/ORN - MAX	12.5	5	No Data	22.4	35.0	N/F	
'	Backpack Sprayer	TURF/ORN - MIN	7.5	7	No Data	26.7	41.7	N/F	
		TURF/ORN - MAX	12.5	7	No Data	16.0	25.0	N/F	
		TURF/ORN - MIN	7.5	5	25.2	259.3	444.4	N/F	
	8 Low Pressure/High volume	TURF/ORN - MAX	12.5	5	15.1	155.6	266.7	N/F	
٥	Turfgun	TURF/ORN - MIN	7.5	7	18.0	185.2	317.5	N/F	
		TURF/ORN - MAX	12.5	7	10.8	111.1	190.5	N/F	
9	Duch time Creatiles Careedes	TURF/ORN - MIN	7.5	5	32.2	73.5	133.3	N/F	
9	Push-type Granular Spreader	TURF/ORN - MAX	12.5	5	19.3	44.1	80.0	N/F	
10	Bellygrinder	TURF/ORN - MIN	7.5	5	9.3	10.0	16.4	N/F	
		TURF/ORN - MAX	12.5	5	5.6	6.0	9.8	N/F	
			HOMEO'	WNER MIXER/LO	DADER/APPLICATO	DRS			
9	Push type Granular Spreader	TURF/ORN - MIN	7.5	0.5	311.1	N/F	N/F	N/F	
9	Push-type Granular Spreader	TURF/ORN - MAX	12.5	0.5	186.7	N/F	N/F	N/F	
10	Bellygrinder	TURF/ORN - MIN	7.5	0.5	8.5	N/F	N/F	N/F	
10	Deliygillidei	TURF/ORN - MAX	12.5	0.5	5.1	N/F	N/F	N/F	

		APPEI	NDIX A/TAE	BLE 8: BENSU	LIDE MOEs ATTR	IBUTABLE TO INHAL	ATION EXPOSUR	RE		
			EXPOSUR	RE FACTORS		INHALATION I	MOEs FOR VARY	ING LEVELS OF PR	OTECTION	
SCEN.	SCEN. DESCRIPTOR	CROP TYPE		ACRES	SHORT-TE	RM EXPOSURE DU	RATIONS	INTERMEDIATE-	TERM EXPOSURE	DURATIONS
		OR TARGET	RATE	OR GALLONS	BASELINE	WITH RESPIRATOR	ENG. CONTROLS	BASELINE	WITH RESPIRATOR	ENG. CONTROLS
				occ	UPATIONAL MIXE	ER/LOADERS				
		AG - MIN	3	350	305.6	3055.6	4417.7	27.8	277.8	401.6
1a	Mixing/loading Liquids for	AG - MIN	3	40	2673.6	26736.1	38654.6	243.1	2430.6	3514.1
Ιά	Chemigation	AG - MAX	6	350	152.8	1527.8	2208.8	13.9	138.9	200.8
		AG - MAX	6	40	1336.8	13368.1	19327.3	121.5	1215.3	1757.0
		AG - MIN	3	80	1336.8	13368.1	19327.3	121.5	1215.3	1757.0
1h	1b Mixing/loading Liquids for Groundboom Application	AG - MAX	6	80	668.4	6684.0	9663.7	60.8	607.6	878.5
ID		TURF/ORN - MIN	7.5	40	1069.4	10694.4	15461.8	97.2	972.2	1405.6
		TURF/ORN - MAX	12.5	40	641.7	6416.7	9277.1	58.3	583.3	843.4
4.5	Mixing/loading Liquids for	TURF/ORN - MIN	7.5	50	855.6	8555.6	12369.5	77.8	777.8	1124.5
1c	Professional Turf Application	TURF/ORN - MAX	12.5	50	513.3	5133.3	7421.7	46.7	466.7	674.7
	Loading Granulars for	TURF/ORN - MIN	7.5	40	754.9	7549.0	37745.1	68.6	686.3	3431.4
2	Tractor Drawn Spreader Application	TURF/ORN - MAX	12.5	40	452.9	4529.4	22647.1	41.2	411.8	2058.8
			•	ОС	CUPATIONAL API	PLICATORS	•			
		AG - MIN	3	80	2167.8	21677.9	37306.2	197.1	1970.7	3391.5
3	Applying Sprays With a	AG - MAX	6	80	1083.9	10839.0	18653.1	98.5	985.4	1695.7
3	Groundboom Sprayer	TURF/ORN - MIN	7.5	40	1734.2	17342.3	29845.0	157.7	1576.6	2713.2
		TURF/ORN - MAX	12.5	40	1040.5	10405.4	17907.0	94.6	945.9	1627.9
4	Applying Granulars With a	TURF/ORN - MIN	7.5	40	1069.4	10694.4	5833.3	97.2	972.2	530.3
4	Tractor-Drawn Spreader	TURF/ORN - MAX	12.5	40	641.7	6416.7	3500.0	58.3	583.3	318.2
				OCCUPATION	ONAL MIXER/LOA	DER/APPLICATORS				
		TURF/ORN - MIN	7.5	5	342.2	3422.2	N/F	31.1	311.1	N/F
5	Low Pressure Handwand	TURF/ORN - MAX	12.5	5	205.3	2053.3	N/F	18.7	186.7	N/F
3	LOW I 1633UIE HAHUWAHU	TURF/ORN - MIN	7.5	7	244.4	2444.4	N/F	22.2	222.2	N/F
		TURF/ORN - MAX	12.5	7	146.7	1466.7	N/F	13.3	133.3	N/F
6	High Pressure Handwand	TURF/ORN/OCC	0.16	1000	20.1	200.5	N/F	1.8	18.2	N/F

		APPEI	NDIX A/TAE	BLE 8: BENSU	LIDE MOEs ATTR	IBUTABLE TO INHAL	ATION EXPOSUR	RE		
			EXPOSUR	RE FACTORS		INHALATION I	MOEs FOR VARY	ING LEVELS OF PR	OTECTION	
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET		ACRES	SHORT-TE	ERM EXPOSURE DU	RATIONS	INTERMEDIATE-TERM EXPOSURE DURATIONS		
		OR TARGET	RATE	OR GALLONS	BASELINE	## RESPIRATOR CONTROLS BASELINE RESPIRATOR CONTROLS 3422.2 N/F 31.1 311.	ENG. CONTROLS			
		TURF/ORN - MIN	7.5	5	342.2	3422.2	N/F	31.1	311.1	N/F
7	7 Backpack Sprayer	TURF/ORN - MAX	12.5	5	205.3	2053.3	N/F	18.7	186.7	N/F
_ ′	Баскраск эргауег	TURF/ORN - MIN	7.5	7	244.4	2444.4	N/F	22.2	222.2	N/F
		TURF/ORN - MAX	12.5	7	146.7	1466.7	N/F	13.3	133.3	N/F
		TURF/ORN - MIN	7.5	5	3948.7	39487.2	N/F	359.0	3589.7	N/F
8	Low Pressure/High volume	TURF/ORN - MAX	12.5	5	2369.2	23692.3	N/F	215.4	2153.8	N/F
	Turfgun	TURF/ORN - MIN	7.5	7	2820.5	28205.1	N/F	256.4	2564.1	N/F
		TURF/ORN - MAX	12.5	7	1692.3	16923.1	N/F	153.8	1538.5	N/F
9	Push-type Granular	TURF/ORN - MIN	7.5	5	1629.6	16296.3	N/F	148.1	1481.5	N/F
9	Spreader	TURF/ORN - MAX	12.5	5	977.8	9777.8	N/F	88.9	888.9	N/F
10	Bellygrinder	TURF/ORN - MIN	7.5	5	165.6	1655.9	N/F	15.1	150.5	N/F
10	bellygillidel	TURF/ORN - MAX	12.5	5	99.4	993.5	N/F	9.0	90.3	N/F
				HOMEOWI	NER MIXER/LOAD	ER/APPLICATORS				
9	Push-type Granular	TURF/ORN - MIN	7.5	0.5	16296.3	N/F	N/F	N/A	N/F	N/F
9	Spreader	TURF/ORN - MAX	12.5	0.5	9777.8	N/F	N/F	N/A	N/F	N/F
10	Pollugrinder	TURF/ORN - MIN	7.5	0.5	1655.9	N/F	N/F	N/A	N/F	N/F
10	Bellygrinder	TURF/ORN - MAX	12.5	0.5	993.5	N/F	N/F	N/A	N/F	N/F

		APPENDIX A	/TABLE 9: B	ENSULIDE MOEs	ATTRIBUTABLE	TO COMBINED DE	RMAL AND INHALA	ATION EXPOSURES			
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSUI RATE	RE FACTORS ACRES OR GALLONS	BASELINE	SINGLE LAYER, GLOVES & NO RESPIRATOR	SINGLE LAYER, GLOVES & RESPIRATOR	DOUBLE LAYER, GLOVES & NO RESPIRATOR	DOUBLE LAYER, GLOVES & RESPIRATOR	ENG. CONTROLS	
					RT-TERM EXPO	SURE DURATIONS					
	SHORT-TERM OCCUPATIONAL MIXER/LOADERS										
		AG - MIN	3	350	1.1	98.3	138.4	119.4	184.3	356.3	
	Mixing/loading	AG - MIN	3	40	10.0	860.1	1210.7	1045.1	1612.2	3117.9	
1a	1a Liquids for Chemigation	AG - MAX	6	350	0.6	49.2	69.2	59.7	92.1	178.2	
		AG - MAX	6	40	5.0	430.1	605.3	522.5	806.1	1559.0	
		AG - MIN	3	80	5.0	430.1	605.3	522.5	806.1	1559.0	
	Mixing/loading	AG - MAX	6	80	2.5	215.0	302.7	261.3	403.1	779.5	
1b	Liquids for Groundboom Application	TURF/ORN - MIN	7.5	40	4.0	344.1	484.3	418.0	644.9	1247.2	
	Аррисацоп	TURF/ORN - MAX	12.5	40	2.4	206.4	290.6	250.8	386.9	748.3	
1c	Mixing/loading Liquids for	TURF/ORN - MIN	7.5	50	3.2	275.2	387.4	334.4	515.9	997.7	
10	Professional Turf Application	TURF/ORN - MAX	12.5	50	1.9	165.1	232.5	200.7	309.5	598.6	
2	Loading Granulars for Tractor Drawn	TURF/ORN - MIN	7.5	40	489.1	521.9	1381.4	618.8	2359.1	24453.8	
2	Spreader Application	TURF/ORN - MAX	12.5	40	293.4	313.1	828.8	371.3	1415.4	14672.3	
				SHORT	TERM OCCUPAT	TIONAL APPLICATO	ORS				
		AG - MIN	3	80	703.6	703.6	993.9	822.7	1249.4	2705.2	
	Applying Sprays	AG - MAX	6	80	351.8	351.8	497.0	411.3	624.7	1352.6	
3	With a Groundboom Sprayer	TURF/ORN - MIN	7.5	40	562.9	562.9	795.1	658.1	999.5	2164.1	
		TURF/ORN - MAX	12.5	40	337.7	337.7	477.1	394.9	599.7	1298.5	
4	Applying Granulars With a	TURF/ORN - MIN	7.5	40	558.0	644.2	1407.2	782.5	2291.7	2845.5	
4	Tractor-Drawn Spreader	TURF/ORN - MAX	12.5	40	334.8	386.5	844.3	469.5	1375.0	1707.3	

		APPENDIX A	/TABLE 9: B	ENSULIDE MOEs	ATTRIBUTABLE	TO COMBINED DE	RMAL AND INHALA	ATION EXPOSURES		
SCEN.	SCEN.	CROP TYPE	EXPOSU	RE FACTORS	BASELINE	SINGLE LAYER, GLOVES	SINGLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	ENG.
002iti.	DESCRIPTOR	OR TARGET	RATE	ACRES OR ACRES OR A NO	& NO RESPIRATOR	DECDIDATOR	& NO RESPIRATOR	& RESPIRATOR	CONTROLS	
				SHORT-TERM O	CCUPATIONAL N	/IIXER/LOADER/AP	PLICATORS			
		TURF/ORN - MIN	7.5	5	0.9	132.8	204.1	145.2	234.9	N/F
5	Low Pressure	TURF/ORN - MAX	12.5	5	0.6	79.7	122.5	87.1	141.0	N/F
Ü	Handwand	TURF/ORN - MIN	7.5	7	0.7	94.9	145.8	103.7	167.8	N/F
		TURF/ORN - MAX	12.5	7	0.4	56.9	87.5	62.2	100.7	N/F
6	High Pressure Handwand	TURF/ORN/O CC	0.16	1000	No Data	6.1	8.4	8.1	12.8	N/F
		TURF/ORN - MIN	7.5	5	No Data	33.7	36.9	49.8	57.4	N/F
7	Backpack Sprayer	TURF/ORN - MAX	12.5	5	No Data	20.2	22.2	29.9	34.4	N/F
,	Баскраск Эргауег	TURF/ORN - MIN	7.5	7	No Data	24.0	26.4	35.6	41.0	N/F
		TURF/ORN - MAX	12.5	7	No Data	14.4	15.8	21.4	24.6	N/F
		TURF/ORN - MIN	7.5	5	25.1	243.3	257.6	399.5	439.5	N/F
8	Low Pressure/High	TURF/ORN - MAX	12.5	5	15.0	146.0	154.5	239.7	263.7	N/F
8	volume Turfgun	TURF/ORN - MIN	7.5	7	17.9	173.8	184.0	285.3	313.9	N/F
		TURF/ORN - MAX	12.5	7	10.7	104.3	110.4	171.2	188.4	N/F
9	Push-type Granular	TURF/ORN - MIN	7.5	5	31.6	70.3	73.2	123.2	132.3	N/F
9	Spreader	TURF/ORN - MAX	12.5	5	18.9	42.2	43.9	74.0	79.4	N/F

		APPENDIX A	/TABLE 9: B	ENSULIDE MOEs	ATTRIBUTABLE	TO COMBINED DE	RMAL AND INHALA	ATION EXPOSURES		
SCEN.	SCEN.	CROP TYPE	EXPOSUI	RE FACTORS	BASELINE	SINGLE LAYER, GLOVES	SINGLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	ENG.
SCEN.	DESCRIPTOR	OR TARGET	RATE	ACRES OR GALLONS	DAGLEINE	& NO RESPIRATOR	& RESPIRATOR	& NO RESPIRATOR	& RESPIRATOR	CONTROLS
40	Della serie de s	TURF/ORN - MIN	7.5	5	8.8	9.5	10.0	14.9	16.2	N/F
10	Bellygrinder	TURF/ORN - MAX	12.5	5	5.3	5.7	6.0	8.9	9.7	N/F
	•			SHORT-TERM I	HOMEOWNER M	XER/LOADER/APF	PLICATORS			
0	Push-type Granular	TURF/ORN - MIN	7.5	0.5	305.3	N/A	N/A	N/A	N/A	N/A
9	Spreader	TURF/ORN - MAX	12.5	0.5	183.2	N/A	N/A	N/A	N/A	N/A
10	Dollygrinder	TURF/ORN - MIN	7.5	0.5	8.4	N/A	N/A	N/A	N/A	N/A
10	Bellygrinder	TURF/ORN - MAX	12.5	0.5	5.1	N/A	N/A	N/A	N/A	N/A
				IN.	TERMEDIATE-TE	RM SUMMARIES				
				INTERMEDIA	TE-TERM OCCUI	PATIONAL MIXER/L	OADERS			
		AG - MIN	3	350	1.1	23.3	95.2	24.3	114.9	197.2
1a	Mixing/loading Liquids for	AG - MIN	3	40	9.7	204.0	833.3	212.9	1005.7	1725.8
iu	Chemigation	AG - MAX	6	350	0.6	11.7	47.6	12.2	57.5	98.6
		AG - MAX	6	40	4.8	102.0	416.7	106.4	502.9	862.9
		AG - MIN	3	80	4.8	102.0	416.7	106.4	502.9	862.9
	Mixing/loading	AG - MAX	6	80	2.4	51.0	208.3	53.2	251.4	431.5
1b	Liquids for Groundboom Application	TURF/ORN - MIN	7.5	40	3.9	81.6	333.3	85.2	402.3	690.3
		TURF/ORN - MAX	12.5	40	2.3	49.0	200.0	51.1	241.4	414.2
1c	Mixing/loading Liquids for	TURF/ORN - MIN	7.5	50	3.1	65.3	266.7	68.1	321.8	552.3
10	Professional Turf Application	TURF/ORN - MAX	12.5	50	1.9	39.2	160.0	40.9	193.1	331.4

		APPENDIX A	/TABLE 9: B	ENSULIDE MOEs	ATTRIBUTABLE	TO COMBINED DE	RMAL AND INHALA	ATION EXPOSURES		
SCEN.	SCEN.	CROP TYPE	EXPOSUI	RE FACTORS	BASELINE	SINGLE LAYER, GLOVES	SINGLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	ENG.
30214.	DESCRIPTOR	OR TARGET	RATE	ACRES OR GALLONS		& NO RESPIRATOR	& RESPIRATOR	& NO RESPIRATOR	& RESPIRATOR	CONTROLS
2	Loading Granulars for Tractor Drawn	TURF/ORN - MIN	7.5	40	65.4	66.0	488.1	67.3	571.9	3269.8
2	Spreader Application	TURF/ORN - MAX	12.5	40	39.2	39.6	292.9	40.4	343.1	1961.9
				INTERMEDIA	ATE-TERM OCCL	JPATIONAL APPLIC	CATORS			
		AG - MIN	3	80	165.7	165.7	681.5	171.6	792.6	1568.1
	Applying Sprayo	AG - MAX	6	80	82.9	82.9	340.7	85.8	396.3	784.1
3	Applying Sprays With a Groundboom Sprayer	TURF/ORN - MIN	7.5	40	132.6	132.6	545.2	137.3	634.1	1254.5
		TURF/ORN - MAX	12.5	40	79.5	79.5	327.1	82.4	380.4	752.7
4	Applying Granulars With a	TURF/ORN - MIN	7.5	40	89.7	91.7	607.6	94.1	729.2	484.1
4	Tractor-Drawn Spreader	TURF/ORN - MAX	12.5	40	53.8	55.0	364.6	56.5	437.5	290.5
			INT	ERMEDIATE-TER	M OCCUPATION	IAL MIXER/LOADE	R/APPLICATORS			
		TURF/ORN - MIN	7.5	5	0.9	27.2	127.9	27.7	139.3	N/F
5	Low Pressure	TURF/ORN - MAX	12.5	5	0.5	16.3	76.7	16.6	83.6	N/F
5	Handwand	TURF/ORN - MIN	7.5	7	0.6	19.4	91.3	19.8	99.5	N/F
	-	TURF/ORN - MAX	12.5	7	0.4	11.7	54.8	11.9	59.7	N/F
6	High Pressure Handwand	TURF/ORN/O CC	0.16	1000	No Data	1.5	5.9	1.6	7.8	N/F

		APPENDIX A	/TABLE 9: B	ENSULIDE MOEs	ATTRIBUTABLE	TO COMBINED DE	RMAL AND INHALA	ATION EXPOSURES		
SCEN.	SCEN.	CROP TYPE	EXPOSU	RE FACTORS	BASELINE	SINGLE LAYER, GLOVES	SINGLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	ENG.
SCEN.	DESCRIPTOR	OR TARGET	RATE	ACRES OR GALLONS	DAOLLINE	& NO RESPIRATOR	& RESPIRATOR	& NO RESPIRATOR	& RESPIRATOR	CONTROLS
		TURF/ORN - MIN	7.5	5	No Data	17.0	33.3	20.3	49.1	N/F
7	Dooknook Carover	TURF/ORN - MAX	12.5	5	No Data	10.2	20.0	12.2	29.5	N/F
7	Backpack Sprayer	TURF/ORN - MIN	7.5	7	No Data	12.1	23.8	14.5	35.1	N/F
		TURF/ORN - MAX	12.5	7	No Data	7.3	14.3	8.7	21.1	N/F
		TURF/ORN - MIN	7.5	5	23.6	150.5	241.8	198.6	395.5	N/F
8	Low Pressure/High	TURF/ORN - MAX	12.5	5	14.1	90.3	145.1	119.1	237.3	N/F
8	volume Turfgun	TURF/ORN - MIN	7.5	7	16.8	107.5	172.7	141.8	282.5	N/F
		TURF/ORN - MAX	12.5	7	10.1	64.5	103.6	85.1	169.5	N/F
9	Push-type Granular	TURF/ORN - MIN	7.5	5	26.4	49.1	70.0	70.2	122.3	N/F
9	Spreader	TURF/ORN - MAX	12.5	5	15.9	29.5	42.0	42.1	73.4	N/F
10	Dollygrinder	TURF/ORN - MIN	7.5	5	5.8	6.0	9.4	7.8	14.8	N/F
10	Bellygrinder	TURF/ORN - MAX	12.5	5	3.5	3.6	5.6	4.7	8.9	N/F
			IN	TERMEDIATE-TE	RM HOMEOWNE	R MIXER/LOADER	/APPLICATORS			
9	Push-type Granular	TURF/ORN - MIN	7.5	0.5	N/A	N/A	N/A	N/A	N/A	N/A
9	Spreader	TURF/ORN - MAX	12.5	0.5	N/A	N/A	N/A	N/A	N/A	N/A
10	Bellygrinder	TURF/ORN - MIN	7.5	0.5	N/A	N/A	N/A	N/A	N/A	N/A
10	Bellygrinder	TURF/ORN - MAX	12.5	0.5	N/A	N/A	N/A	N/A	N/A	N/A

		APPENDIX A/TABI	LE 10: BENSULIDE	MOEs ATTRIBU	TABLE TO COMBI	NED DERMAL AN	ND INHALATION EX	POSURES		
SCEN	SCEN. DESCRIPTOR	CROP TYPE	EXPOSURE	FACTORS	BASELINE	SINGLE LAYER, GLOVES	SINGLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	DOUBLE LAYER, GLOVES	ENG.
OOLIV.	COLN. DECOMIT TON	OR TARGET	RATE	ACRES OR GALLONS		& NO RESPIRATOR	& RESPIRATOR	& NO RESPIRATOR	& RESPIRATOR	CONTROLS
				SHORT-TERM	EXPOSURE DURA	ATIONS				
		AG - MIN	3	80	5.0	266.9	376.2	319.6	490.0	989.0
1b & 3	Groundboom	AG - MAX	6	80	2.5	133.5	188.1	159.8	245.0	494.5
10 & 3	Application	TURF/ORN - MIN	7.5	40	4.0	213.5	301.0	255.6	392.0	791.2
		TURF/ORN - MAX	12.5	40	2.4	128.1	180.6	153.4	235.2	474.7
2 & 4	Tractor Drawn	TURF/ORN - MIN	7.5	40	260.6	288.3	697.1	345.5	1162.4	2548.9
2 & 4	Spreader Application	TURF/ORN - MAX	12.5	40	156.4	173.0	418.3	207.3	697.5	1529.4
			IN	TERMEDIATE-TE	RM EXPOSURE [DURATIONS				
		AG - MIN	3	80	4.7	63.1	258.6	65.7	307.7	556.6
1b & 3	Groundboom	AG - MAX	6	80	2.3	31.6	129.3	32.8	153.8	278.3
10 & 3	Application	TURF/ORN - MIN	7.5	40	3.8	50.5	206.9	52.6	246.1	445.3
		TURF/ORN - MAX	12.5	40	2.3	30.3	124.1	31.5	147.7	267.2
28.4	Tractor Drawn	TURF/ORN - MIN	7.5	40	37.8	38.4	270.7	39.2	320.5	421.7
204	2 & 4 Spreader Application	TURF/ORN - MAX	12.5	40	22.7	23.0	162.4	23.5	192.3	253.0

APPENDIX B BENSULIDE NON-DIETARY POST-APPLICATION EXPOSURE & RISK ASSESSMENT FOR ADULTS

Appendix B	3/Table 1: Analy	sis of Bensulio	de Turf Transfera	ble Residue (TTR)	Data							
Sample	Replicate		Ben	sulide			Bensulide Oxo	on		Total TTR		Oxon
Days	Number	(Total ug)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(Total ug)	(ug/cm2)	Ln (ug/cm2)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(%tage)
0	Α	2922.00	0.51353	0.56649	-0.66644	62.00	0.01090	-4.51933	0.52443	0.58032	-0.64545	2.08
0	В	2972.00	0.52232		-0.64948	79.00	0.01388	-4.27702	0.53620		-0.62324	2.59
0	С	3776.00	0.66362		-0.41004	95.10	0.01671	-4.09154	0.68033		-0.38517	2.46
0.42	Α	721.00	0.12671	0.17698	-2.06583	20.80	0.00366	-5.61151	0.13037	0.18173	-2.03739	2.80
0.42	В	1362.00	0.23937		-1.42976	33.20	0.00583	-5.14392	0.24520		-1.40567	2.38
0.42	С	938.00	0.16485		-1.80272	27.20	0.00478	-5.34325	0.16963		-1.77413	2.82
1	А	264.00	0.04640	0.06192	-3.07052	4.00	0.00070	-7.26017	0.04710	0.06262	-3.05548	N/A
1	В	227.00	0.03989		-3.22152	4.00	0.00070	-7.26017	0.04060		-3.20405	N/A
1	С	566.00	0.09947		-2.30787	4.00	0.00070	-7.26017	0.10018		-2.30083	N/A
2	Α	643.00	0.11301	0.07721	-2.18032	4.00	0.00070	-7.26017	0.11371	0.07791	-2.17412	N/A
2	В	558.00	0.09807		-2.32211	4.00	0.00070	-7.26017	0.09877		-2.31496	N/A
2	С	117.00	0.02056		-3.88429	4.00	0.00070	-7.26017	0.02127		-3.85067	N/A
3	Α	75.90	0.01334	0.03485	-4.31705	4.00	0.00070	-7.26017	0.01404	0.03555	-4.26569	N/A
3	В	298.00	0.05237		-2.94937	4.00	0.00070	-7.26017	0.05308		-2.93604	N/A
3	С	221.00	0.03884		-3.24830	4.00	0.00070	-7.26017	0.03954		-3.23037	N/A
4	А	493.00	0.08664	0.08811	-2.44596	16.40	0.00288	-5.84918	0.08953	0.09125	-2.41323	3.22
4	В	528.00	0.09279		-2.37737	18.60	0.00327	-5.72330	0.09606		-2.34275	3.40
4	С	483.00	0.08489		-2.46645	18.60	0.00327	-5.72330	0.08815		-2.42866	3.71
5	Α	1093.00	0.19209	0.09725	-1.64978	54.00	0.00949	-4.65748	0.20158	0.10257	-1.60156	4.71
5	В	232.00	0.04077		-3.19973	17.00	0.00299	-5.81325	0.04376		-3.12901	6.83
5	С	335.00	0.05888		-2.83233	19.90	0.00350	-5.65575	0.06237		-2.77463	5.61
6	Α	286.00	0.05026	0.05167	-2.99047	9.58	0.00168	-6.38679	0.05195	0.05329	-2.95753	3.24
6	В	271.00	0.04763		-3.04435	9.28	0.00163	-6.41860	0.04926		-3.01068	3.31
6	С	325.00	0.05712		-2.86264	8.81	0.00155	-6.47058	0.05867		-2.83589	2.64
7	Α	65.50	0.01151	0.03612	-4.46442	4.00	0.00070	-7.26017	0.01221	0.03739	-4.40514	5.76
7	В	428.00	0.07522		-2.58734	13.80	0.00243	-6.02180	0.07764		-2.55561	3.12
7	С	123.00	0.02162		-3.83428	4.00	0.00070	-7.26017	0.02232		-3.80228	N/A
10	Α	119.00	0.02091	0.01738	-3.86734	4.00	0.00070	-7.26017	0.02162	0.01808	-3.83428	N/A
10	В	144.00	0.02531		-3.67665	4.00	0.00070	-7.26017	0.02601		-3.64925	N/A
10	С	33.60	0.00591		-5.13194	4.00	0.00070	-7.26017	0.00661		-5.01946	N/A
14	Α	18.80	0.00330	0.00195	-5.71261	4.00	0.00070	-7.26017	0.00401	0.00265	-5.51970	N/A
14	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
14	С	10.50	0.00185		-6.29509	4.00	0.00070	-7.26017	0.00255		-5.97232	N/A
21	Α	4.00	0.00070	N/A	-7.26017	4.00	0.00070	-7.26017	0.00141	N/A	-6.56702	N/A
21	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
21	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A

Appendix E	Appendix B/Table 1: Analysis of Bensulide Turf Transferable Residue (TTR) Data												
Sample	Replicate		Ben	sulide			Bensulide Oxo	on		Total TTR		Oxon	
Days	(Total ag) (ag/oniz)		Average (ug/cm2)	Ln (ug/cm2)	(Total ug)	(ug/cm2)	Ln (ug/cm2)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(%tage)		
28	Α	4.00	0.00070	N/A	-7.26017	4.00	0.00070	-7.26017	0.00141	N/A	-6.56702	N/A	
28	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A	
28	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A	
35	Α	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A	
35	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A	
35	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A	

	A	ppendix B/Table 2: MOEs Attr	ibutable to Bensulide Exposure F	For Adults Engaged in Activities	on Treated Turf	
DAT		Bensulide TTR n/cm2)		t Dose kg/day)	Adult	MOEs
	Lowest Rate	Highest Rate	Light Activity & Lowest Rate	High Activity & Highest Rate	Light Activity & Lowest Rate	High Activity & Highest Rate
0	0.336401	0.566500	0.01922	0.32371	2601	154.5
0.25	0.311719	0.524934	0.01781	0.29996	2807	166.7
0.5	0.288847	0.486418	0.01651	0.27795	3029	179.9
0.75	0.267654	0.450728	0.01529	0.25756	3269	194.1
1	0.248015	0.417657	0.01417	0.23866	3528	209.5
2	0.182851	0.307922	0.01045	0.17596	4785	284.2
3	0.134809	0.227018	0.00770	0.12972	6491	385.4
4	0.099389	0.167371	0.00568	0.09564	8804	522.8
5	0.073275	0.123396	0.00419	0.07051	11941	709.1
6	0.054023	0.090975	0.00309	0.05199	16197	961.8
7	0.039829	0.067072	0.00228	0.03833	21969	1304.6
8	0.029364	0.049449	0.00168	0.02826	29798	1769.5
9	0.021649	0.036457	0.00124	0.02083	40417	2400.1
10	0.015961	0.026878	0.00091	0.01536	54821	3255.4
11	0.011767	0.019816	0.00067	0.01132	74358	4415.6
12	0.008676	0.014610	0.00050	0.00835	100858	5989.2
13	0.006396	0.010771	0.00037	0.00615	136801	8123.6
14	0.004716	0.007941	0.00027	0.00454	185553	11018.6
AVERAGE	N/A	N/A	0.00678	0.11416	7376	438.0
			Actual TTRs			
0	0.336401	0.566500	0.01922	0.32371	2601	154.5
0.42	0.105095	0.176980	0.00601	0.10113	8326	494.4
1	0.036770	0.061920	0.00210	0.03538	23797	1413.1
2	0.045849	0.077210	0.00262	0.04412	19084	1133.3
3	0.020695	0.034850	0.00118	0.01991	42281	2510.8
4	0.052322	0.088110	0.00299	0.05035	16723	993.1
5	0.057749	0.097250	0.00330	0.05557	15152	899.7
6	0.030683	0.051670	0.00175	0.02953	28518	1693.4
7	0.021449	0.036120	0.00123	0.02064	40795	2422.5
10	0.010321	0.017380	0.00059	0.00993	84781	5034.5

Appendix B/Table 3: MOEs Attributable to Bensulide and Bensulide Oxon Exposure For Adults Engaged in Activities on Treated Turf

DAT		Total TTR /cm2)		lt Dose /kg/day)	Adu	ult MOEs
	MIN. ORN	MAX. ORN	Light Activity &	High Activity &	Light Activity &	High Activity &
			Lowest Rate	Highest Rate	Lowest Rate	Highest Rate
0	0.344608	0.580320	0.01969	0.33161	2539	150.8
0.25	0.320941	0.540464	0.01834	0.30884	2726	161.9
0.5	0.298898	0.503345	0.01708	0.28763	2927	173.8
0.75	0.278370	0.468775	0.01591	0.26787	3143	186.7
1	0.259252	0.436580	0.01481	0.24947	3375	200.4
2	0.195038	0.328443	0.01115	0.18768	4486	266.4
3	0.146729	0.247091	0.00838	0.14119	5963	354.1
4	0.110385	0.185889	0.00631	0.10622	7927	470.7
5	0.083044	0.139846	0.00475	0.07991	10537	625.7
6	0.062475	0.105207	0.00357	0.06012	14006	831.7
7	0.047000	0.079148	0.00269	0.04523	18617	1105.5
8	0.035359	0.059544	0.00202	0.03403	24746	1469.5
9	0.026601	0.044796	0.00152	0.02560	32894	1953.3
10	0.020012	0.033700	0.00114	0.01926	43724	2596.4
11	0.015055	0.025353	0.00086	0.01449	58120	3451.3
12	0.011326	0.019073	0.00065	0.01090	77255	4587.6
13	0.008521	0.014349	0.00049	0.00820	102690	6098.0
14	0.006410	0.010795	0.00037	0.00617	136500	8105.7
AVERAGE	N/A	N/A	0.00721	0.12136	6938	412.0
			Actual TTRs			
0	0.336401	0.580320	0.01922	0.33161	2601	150.8
0.42	0.105095	0.181730	0.00601	0.10385	8326	481.5
1	0.036770	0.062620	0.00210	0.03578	23797	1397.3
2	0.045849	0.077910	0.00262	0.04452	19084	1123.1
3	0.020695	0.035550	0.00118	0.02031	42281	2461.3
4	0.052322	0.091250	0.00299	0.05214	16723	958.9
5	0.057749	0.102570	0.00330	0.05861	15152	853.1
6	0.030683	0.053290	0.00175	0.03045	28518	1642.0
7	0.021449	0.037390	0.00123	0.02137	40795	2340.2
10	0.010321	0.018080	0.00059	0.01033	84781	4839.6

APPENDIX C BENSULIDE NON-DIETARY POST-APPLICATION EXPOSURE & RISK ASSESSMENT FOR CHILDREN

	Appendix C/Table 1: Analysis of Bensulide Turf Transferable Residue (TTR) Data											
Sample	Replicate		Ben	sulide			Bensulide Oxo	on		Total TTR		Oxon
Days	Number	(Total ug)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(Total ug)	(ug/cm2)	Ln (ug/cm2)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(%tage)
0	А	2922.00	0.51353	0.56649	-0.66644	62.00	0.01090	-4.51933	0.52443	0.58032	-0.64545	2.08
0	В	2972.00	0.52232		-0.64948	79.00	0.01388	-4.27702	0.53620		-0.62324	2.59
0	С	3776.00	0.66362		-0.41004	95.10	0.01671	-4.09154	0.68033		-0.38517	2.46
0.42	А	721.00	0.12671	0.17698	-2.06583	20.80	0.00366	-5.61151	0.13037	0.18173	-2.03739	2.80
0.42	В	1362.00	0.23937		-1.42976	33.20	0.00583	-5.14392	0.24520		-1.40567	2.38
0.42	С	938.00	0.16485		-1.80272	27.20	0.00478	-5.34325	0.16963		-1.77413	2.82
1	А	264.00	0.04640	0.06192	-3.07052	4.00	0.00070	-7.26017	0.04710	0.06262	-3.05548	N/A
1	В	227.00	0.03989		-3.22152	4.00	0.00070	-7.26017	0.04060		-3.20405	N/A
1	С	566.00	0.09947		-2.30787	4.00	0.00070	-7.26017	0.10018		-2.30083	N/A
2	А	643.00	0.11301	0.07721	-2.18032	4.00	0.00070	-7.26017	0.11371	0.07791	-2.17412	N/A
2	В	558.00	0.09807		-2.32211	4.00	0.00070	-7.26017	0.09877		-2.31496	N/A
2	С	117.00	0.02056		-3.88429	4.00	0.00070	-7.26017	0.02127		-3.85067	N/A
3	А	75.90	0.01334	0.03485	-4.31705	4.00	0.00070	-7.26017	0.01404	0.03555	-4.26569	N/A
3	В	298.00	0.05237		-2.94937	4.00	0.00070	-7.26017	0.05308		-2.93604	N/A
3	С	221.00	0.03884		-3.24830	4.00	0.00070	-7.26017	0.03954		-3.23037	N/A
4	А	493.00	0.08664	0.08811	-2.44596	16.40	0.00288	-5.84918	0.08953	0.09125	-2.41323	3.22
4	В	528.00	0.09279		-2.37737	18.60	0.00327	-5.72330	0.09606		-2.34275	3.40
4	С	483.00	0.08489		-2.46645	18.60	0.00327	-5.72330	0.08815		-2.42866	3.71
5	А	1093.00	0.19209	0.09725	-1.64978	54.00	0.00949	-4.65748	0.20158	0.10257	-1.60156	4.71
5	В	232.00	0.04077		-3.19973	17.00	0.00299	-5.81325	0.04376		-3.12901	6.83
5	С	335.00	0.05888		-2.83233	19.90	0.00350	-5.65575	0.06237		-2.77463	5.61
6	Α	286.00	0.05026	0.05167	-2.99047	9.58	0.00168	-6.38679	0.05195	0.05329	-2.95753	3.24
6	В	271.00	0.04763		-3.04435	9.28	0.00163	-6.41860	0.04926		-3.01068	3.31
6	С	325.00	0.05712		-2.86264	8.81	0.00155	-6.47058	0.05867		-2.83589	2.64
7	А	65.50	0.01151	0.03612	-4.46442	4.00	0.00070	-7.26017	0.01221	0.03739	-4.40514	5.76
7	В	428.00	0.07522		-2.58734	13.80	0.00243	-6.02180	0.07764		-2.55561	3.12
7	С	123.00	0.02162		-3.83428	4.00	0.00070	-7.26017	0.02232		-3.80228	N/A
10	А	119.00	0.02091	0.01738	-3.86734	4.00	0.00070	-7.26017	0.02162	0.01808	-3.83428	N/A
10	В	144.00	0.02531		-3.67665	4.00	0.00070	-7.26017	0.02601]	-3.64925	N/A
10	С	33.60	0.00591		-5.13194	4.00	0.00070	-7.26017	0.00661		-5.01946	N/A
14	А	18.80	0.00330	0.00195	-5.71261	4.00	0.00070	-7.26017	0.00401	0.00265	-5.51970	N/A
14	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
14	С	10.50	0.00185		-6.29509	4.00	0.00070	-7.26017	0.00255		-5.97232	N/A
21	А	4.00	0.00070	N/A	-7.26017	4.00	0.00070	-7.26017	0.00141	N/A	-6.56702	N/A
21	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
21	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A

Appendix C/Table 1: Analysis of Bensulide Turf Transferable Residue (TTR) Data												
Sample	Replicate		Ben	sulide			Bensulide Oxo	on		Total TTR		Oxon
Days	Number	(Total ug)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(Total ug)	(ug/cm2)	Ln (ug/cm2)	(ug/cm2)	Average (ug/cm2)	Ln (ug/cm2)	(%tage)
28	Α	4.00	0.00070	N/A	-7.26017	4.00	0.00070	-7.26017	0.00141	N/A	-6.56702	N/A
28	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
28	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
35	Α	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
35	В	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A
35	С	4.00	0.00070		-7.26017	4.00	0.00070	-7.26017	0.00141		-6.56702	N/A

		Appendix C/Table 2: Derma	al Risks From Bensulide Attributa	ble to Contact With Treated T	urf	
DAT		ensulide TTR ug/cm2)	Child D (mg/kg/		Chilo	IMOE
	MIN. ORN	MAX. ORN	SOP TC MIN. ORN	SOP TC MAX. ORN	SOP TC MIN. ORN	SOP TC MAX. ORN
0	0.336401	0.566500	0.39023	0.65714	128	76.1
0.25	0.311719	0.524934	0.36159	0.60892	138	82.1
0.5	0.288847	0.486418	0.33506	0.56425	149	88.6
0.75	0.267654	0.450728	0.31048	0.52285	161	95.6
1	0.248015	0.417657	0.28770	0.48448	174	103.2
2	0.182851	0.307922	0.21211	0.35719	236	140.0
3	0.134809	0.227018	0.15638	0.26334	320	189.9
4	0.099389	0.167371	0.11529	0.19415	434	257.5
5	0.073275	0.123396	0.08500	0.14314	588	349.3
6	0.054023	0.090975	0.06267	0.10553	798	473.8
7	0.039829	0.067072	0.04620	0.07780	1082	642.6
8	0.029364	0.049449	0.03406	0.05736	1468	871.7
9	0.021649	0.036457	0.02511	0.04229	1991	1182.3
10	0.015961	0.026878	0.01851	0.03118	2701	1603.7
11	0.011767	0.019816	0.01365	0.02299	3663	2175.2
12	0.008676	0.014610	0.01006	0.01695	4968	2950.3
13	0.006396	0.010771	0.00742	0.01249	6739	4001.8
14	0.004716	0.007941	0.00547	0.00921	9141	5427.9
AVERAGE	N/A	N/A	0.13761	0.23174	363	215.8
			Actual TTR			
0	0.336401	0.566500	0.39023	0.65714	128	76.1
0.42	0.105095	0.176980	0.12191	0.20530	410	243.5
1	0.036770	0.061920	0.04265	0.07183	1172	696.1
2	0.045849	0.077210	0.05319	0.08956	940	558.3
3	0.020695	0.034850	0.02401	0.04043	2083	1236.8
4	0.052322	0.088110	0.06069	0.10221	824	489.2
5	0.057749	0.097250	0.06699	0.11281	746	443.2
6	0.030683	0.051670	0.03559	0.05994	1405	834.2
7	0.021449	0.036120	0.02488	0.04190	2010	1193.3
10	0.010321	0.017380	0.01197	0.02016	4176	2480.1

	Append	ix C/Table 3: Dermal Risks Fro	s From Bensulide and Bensulide Oxon Attributable to Contact With Treated Turf						
DAT	Predicted (I	Total TTR ug/cm2)	Child E (mg/k	Dose kg/day)	Child	MOE			
	MIN. ORN	MAX. ORN	SOP TC MIN. ORN	SOP TC MAX. ORN	SOP TC MIN. ORN	SOP TC MAX. ORN			
0	0.344608	0.580320	0.39975	0.67317	125	74.3			
0.25	0.320941	0.540464	0.37229	0.62694	134	79.8			
0.5	0.298898	0.503345	0.34672	0.58388	144	85.6			
0.75	0.278370	0.468775	0.32291	0.54378	155	91.9			
1	0.259252	0.436580	0.30073	0.50643	166	98.7			
2	0.195038	0.328443	0.22624	0.38099	221	131.2			
3	0.146729	0.247091	0.17021	0.28663	294	174.4			
4	0.110385	0.185889	0.12805	0.21563	390	231.9			
5	0.083044	0.139846	0.09633	0.16222	519	308.2			
6	0.062475	0.105207	0.07247	0.12204	690	409.7			
7	0.047000	0.079148	0.05452	0.09181	917	544.6			
8	0.035359	0.059544	0.04102	0.06907	1219	723.9			
9	0.026601	0.044796	0.03086	0.05196	1620	962.2			
10	0.020012	0.033700	0.02321	0.03909	2154	1279.0			
11	0.015055	0.025353	0.01746	0.02941	2863	1700.1			
12	0.011326	0.019073	0.01314	0.02212	3806	2259.9			
13	0.008521	0.014349	0.00988	0.01664	5059	3003.9			
14	0.006410	0.010795	0.00744	0.01252	6724	3993.0			
AVERAGE	N/A	N/A	0.14629	0.24635	1511	897			
			Actual TTRs						
0	0.336401	0.580320	0.39023	0.67317	128	74.3			
0.42	0.105095	0.181730	0.12191	0.21081	410	237.2			
1	0.036770	0.062620	0.04265	0.07264	1172	688.3			
2	0.045849	0.077910	0.05319	0.09038	940	553.2			
3	0.020695	0.035550	0.02401	0.04124	2083	1212.5			
4	0.052322	0.091250	0.06069	0.10585	824	472.4			
5	0.057749	0.102570	0.06699	0.11898	746	420.2			
6	0.030683	0.053290	0.03559	0.06182	1405	8.808			
7	0.021449	0.037390	0.02488	0.04337	2010	1152.8			
10	0.010321	0.018080	0.01197	0.02097	4176	2384.0			

			Appendix C/Table	4: Risks Attributat	ole to Bensulide Re	sidues From Mouth	ning Bensulide Trea	ted Turf		
DAT		d Bensulide (ug/cm2)	Child [(mg/kg		Ch (% I	ild RfD)		thing at RfD m2)	MOEs For Gra	ass Mouthing
	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN
0	0.336401	0.566500	0.000561	0.000944	0.374	0.629	6688.44	3971.76	26753.8	15887.0
0.25	0.311719	0.524934	0.000520	0.000875	0.346	0.583	7218.05	4286.25	28872.2	17145.0
0.5	0.288847	0.486418	0.000481	0.000811	0.321	0.540	7789.59	4625.65	31158.4	18502.6
0.75	0.267654	0.450728	0.000446	0.000751	0.297	0.501	8406.39	4991.92	33625.6	19967.7
1	0.248015	0.417657	0.000413	0.000696	0.276	0.464	9072.03	5387.19	36288.1	21548.8
2	0.182851	0.307922	0.000305	0.000513	0.203	0.342	12305.08	7307.05	49220.3	29228.2
3	0.134809	0.227018	0.000225	0.000378	0.150	0.252	16690.31	9911.11	66761.2	39644.4
4	0.099389	0.167371	0.000166	0.000279	0.110	0.186	22638.32	13443.18	90553.3	53772.7
5	0.073275	0.123396	0.000122	0.000206	0.081	0.137	30706.05	18234.00	122824.2	72936.0
6	0.054023	0.090975	0.000090	0.000152	0.060	0.101	41648.93	24732.15	166595.7	98928.6
7	0.039829	0.067072	0.000066	0.000112	0.044	0.075	56491.58	33546.07	225966.3	134184.3
8	0.029364	0.049449	0.000049	0.000082	0.033	0.055	76623.78	45501.06	306495.1	182004.2
9	0.021649	0.036457	0.000036	0.000061	0.024	0.041	103930.61	61716.51	415722.4	246866.0
10	0.015961	0.026878	0.000027	0.000045	0.018	0.030	140968.90	83710.75	563875.6	334843.0
11	0.011767	0.019816	0.000020	0.000033	0.013	0.022	191206.74	113543.19	764826.9	454172.8
12	0.008676	0.014610	0.000014	0.000024	0.010	0.016	259348.09	154007.18	1037392.4	616028.7
13	0.006396	0.010771	0.000011	0.000018	0.007	0.012	351773.33	208891.53	1407093.3	835566.1
14	0.004716	0.007941	8000000	0.000013	0.005	0.009	477136.65	283335.30	1908546.6	1133341.2
	_				Actual Bensulide					
0	0.336401	0.566500	0.000561	0.000944	0.374	0.629	6688.44	3971.76	26753.8	15887.0
0.42	0.105095	0.176980	0.000175	0.000295	0.117	0.197	21409.20	12713.30	85636.8	50853.2
1	0.036770	0.061920	0.000061	0.000103	0.041	0.069	61191.86	36337.21	244767.4	145348.8
2	0.045849	0.077210	0.000076	0.000129	0.051	0.086	49073.95	29141.30	196295.8	116565.2
3	0.020695	0.034850	0.000034	0.000058	0.023	0.039	108723.10	64562.41	434892.4	258249.6
4	0.052322	0.088110	0.000087	0.000147	0.058	0.098	43003.06	25536.26	172012.3	102145.0
5	0.057749	0.097250	0.000096	0.000162	0.064	0.108	38961.44	23136.25	155845.8	92545.0
6	0.030683	0.051670	0.000051	0.000086	0.034	0.057	73330.75	43545.58	293323.0	174182.3
7	0.021449	0.036120	0.000036	0.000060	0.024	0.040	104900.33	62292.36	419601.3	249169.4
10	0.010321	0.017380	0.000017	0.000029	0.011	0.019	218009.21	129459.15	872036.8	517836.6
								•		

		Appendix C/Tab	le 5: Risks Attributat	ole to Bensulide and	d Bensulide Oxor	Residues From I	Mouthing Bensulid	e Treated Turf		
DAT	Predicted 7 (ug/c	2 121	Child I (mg/kg		Child ((% RfD)		thing at RfD m2)	MOEs For G	rass Mouthing
	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN
0	0.344608	0.580320	0.000574	0.000967	0.383	0.645	6529.16	3877.17	26116.6	15508.7
0.25	0.320941	0.540464	0.000535	0.000901	0.357	0.601	7010.65	4163.09	28042.6	16652.4
0.5	0.298898	0.503345	0.000498	0.000839	0.332	0.559	7527.64	4470.10	30110.6	17880.4
0.75	0.278370	0.468775	0.000464	0.000781	0.309	0.521	8082.76	4799.74	32331.0	19199.0
1	0.259252	0.436580	0.000432	0.000728	0.288	0.485	8678.82	5153.69	34715.3	20614.8
2	0.195038	0.328443	0.000325	0.000547	0.217	0.365	11536.24	6850.50	46145.0	27402.0
3	0.146729	0.247091	0.000245	0.000412	0.163	0.275	15334.44	9105.96	61337.8	36423.9
4	0.110385	0.185889	0.000184	0.000310	0.123	0.207	20383.17	12104.02	81532.7	48416.1
5	0.083044	0.139846	0.000138	0.000233	0.092	0.155	27094.14	16089.15	108376.5	64356.6
6	0.062475	0.105207	0.000104	0.000175	0.069	0.117	36014.63	21386.36	144058.5	85545.4
7	0.047000	0.079148	0.000078	0.000132	0.052	0.088	47872.11	28427.62	191488.5	113710.5
8	0.035359	0.059544	0.000059	0.000099	0.039	0.066	63633.57	37787.15	254534.3	151148.6
9	0.026601	0.044796	0.000044	0.000075	0.030	0.050	84584.33	50228.22	338337.3	200912.9
10	0.020012	0.033700	0.000033	0.000056	0.022	0.037	112432.94	66765.40	449731.8	267061.6
11	0.015055	0.025353	0.000025	0.000042	0.017	0.028	149450.44	88747.29	597801.8	354989.2
12	0.011326	0.019073	0.000019	0.000032	0.013	0.021	198655.62	117966.52	794622.5	471866.1
13	0.008521	0.014349	0.000014	0.000024	0.009	0.016	264061.15	156805.91	1056244.6	627223.6
14	0.006410	0.010795	0.000011	0.000018	0.007	0.012	351000.84	208432.80	1404003.4	833731.2
				Actual Bensulide	and Bensulide (Oxon TTRs				
0	0.336401	0.580320	0.000561	0.000967	0.374	0.645	6688.44	3877.17	26753.8	15508.7
0.42	0.105095	0.181730	0.000175	0.000303	0.117	0.202	21409.20	12381.00	85636.8	49524.0
1	0.036770	0.062620	0.000061	0.000104	0.041	0.070	61191.86	35931.01	244767.4	143724.0
2	0.045849	0.077910	0.000076	0.000130	0.051	0.087	49073.95	28879.48	196295.8	115517.9
3	0.020695	0.035550	0.000034	0.000059	0.023	0.040	108723.10	63291.14	434892.4	253164.6
4	0.052322	0.091250	0.000087	0.000152	0.058	0.101	43003.06	24657.53	172012.3	98630.1
5	0.057749	0.102570	0.000096	0.000171	0.064	0.114	38961.44	21936.24	155845.8	87745.0
6	0.030683	0.053290	0.000051	0.000089	0.034	0.059	73330.75	42221.81	293323.0	168887.2
7	0.021449	0.037390	0.000036	0.000062	0.024	0.042	104900.33	60176.52	419601.3	240706.1
10	0.010321	0.018080	0.000017	0.000030	0.011	0.020	218009.21	124446.90	872036.8	497787.6

		Appendix C/	Table 6: Risks Attributable	to Bensulide Residues F	From Hand-toMouth Ac	tivity on Bensulide Treated	Turf	
DAT	Predicted	Bensulide TTR (ug/cm2)	Child I (mg/kg		Child	(% RfD)	MOEs For Gr	ass Mouthing
	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN
0	0.336401	0.566500	0.024490	0.041241	16.3	27.5	612.5	363.7
0.25	0.311719	0.524934	0.022693	0.038215	15.1	25.5	661.0	392.5
0.5	0.288847	0.486418	0.021028	0.035411	14.0	23.6	713.3	423.6
0.75	0.267654	0.450728	0.019485	0.032813	13.0	21.9	769.8	457.1
1	0.248015	0.417657	0.018055	0.030405	12.0	20.3	830.8	493.3
2	0.182851	0.307922	0.013312	0.022417	8.9	14.9	1126.8	669.1
3	0.134809	0.227018	0.009814	0.016527	6.5	11.0	1528.4	907.6
4	0.099389	0.167371	0.007236	0.012185	4.8	8.1	2073.1	1231.1
5	0.073275	0.123396	0.005334	0.008983	3.6	6.0	2811.9	1669.8
6	0.054023	0.090975	0.003933	0.006623	2.6	4.4	3814.0	2264.8
7	0.039829	0.067072	0.002900	0.004883	1.9	3.3	5173.2	3072.0
8	0.029364	0.049449	0.002138	0.003600	1.4	2.4	7016.8	4166.8
9	0.021649	0.036457	0.001576	0.002654	1.1	1.8	9517.5	5651.7
10	0.015961	0.026878	0.001162	0.001957	0.8	1.3	12909.2	7665.8
11	0.011767	0.019816	0.000857	0.001443	0.6	1.0	17509.8	10397.7
12	0.008676	0.014610	0.000632	0.001064	0.4	0.7	23749.8	14103.2
13	0.006396	0.010771	0.000466	0.000784	0.3	0.5	32213.7	19129.3
14	0.004716	0.007941	0.000343	0.000578	0.2	0.4	43693.8	25946.5
				Actual Bensulide	e TTRs			
0	0.336401	0.566500	0.024490	0.041241	16.3	27.5	612.5	363.7
0.42	0.105095	0.176980	0.007651	0.012884	5.1	8.6	1960.5	1164.2
1	0.036770	0.061920	0.002677	0.004508	1.8	3.0	5603.7	3327.6
2	0.045849	0.077210	0.003338	0.005621	2.2	3.7	4494.0	2668.6
3	0.020695	0.034850	0.001507	0.002537	1.0	1.7	9956.3	5912.3
4	0.052322	0.088110	0.003809	0.006414	2.5	4.3	3938.0	2338.5
5	0.057749	0.097250	0.004204	0.007080	2.8	4.7	3567.9	2118.7
6	0.030683	0.051670	0.002234	0.003762	1.5	2.5	6715.3	3987.7
7	0.021449	0.036120	0.001561	0.002630	1.0	1.8	9606.3	5704.4
10	0.010321	0.017380	0.000751	0.001265	0.5	0.8	19964.2	11855.2

Appendix C/Table 7: Risks Attributable to Bensulide and Bensulide Oxon Residues From Hand-toMouth Activity on Bensulide Treated Turf								
DAT	Predicted Total TTR (ug/cm2)		Child Dose (mg/kg/day)		Child (% RfD)		MOEs For Grass Mouthing	
	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN	MIN. ORN	MAX. ORN
0	0.344608	0.580320	0.024490	0.042247	16.3	27.5	612.5	355.1
0.25	0.320941	0.540464	0.022693	0.039346	15.1	25.5	661.0	381.2
0.5	0.298898	0.503345	0.021028	0.036644	14.0	23.6	713.3	409.3
0.75	0.278370	0.468775	0.019485	0.034127	13.0	21.9	769.8	439.5
1	0.259252	0.436580	0.018055	0.031783	12.0	20.3	830.8	472.0
2	0.195038	0.328443	0.013312	0.023911	8.9	14.9	1126.8	627.3
3	0.146729	0.247091	0.009814	0.017988	6.5	11.0	1528.4	833.9
4	0.110385	0.185889	0.007236	0.013533	4.8	8.1	2073.1	1108.4
5	0.083044	0.139846	0.005334	0.010181	3.6	6.0	2811.9	1473.4
6	0.062475	0.105207	0.003933	0.007659	2.6	4.4	3814.0	1958.5
7	0.047000	0.079148	0.002900	0.005762	1.9	3.3	5173.2	2603.3
8	0.035359	0.059544	0.002138	0.004335	1.4	2.4	7016.8	3460.4
9	0.026601	0.044796	0.001576	0.003261	1.1	1.8	9517.5	4599.7
10	0.020012	0.033700	0.001162	0.002453	0.8	1.3	12909.2	6114.0
11	0.015055	0.025353	0.000857	0.001846	0.6	1.0	17509.8	8127.0
12	0.011326	0.019073	0.000632	0.001389	0.4	0.7	23749.8	10802.8
13	0.008521	0.014349	0.000466	0.001045	0.3	0.5	32213.7	14359.5
14	0.006410	0.010795	0.000343	0.000786	0.2	0.4	43693.8	19087.3
ActualBensulide and Bensulide Oxon Total TTRs								
0	0.336401	0.580320	0.024490	0.042247	16.3	27.5	612.5	355.1
0.42	0.105095	0.181730	0.007651	0.013230	5.1	8.6	1960.5	1133.8
1	0.036770	0.062620	0.002677	0.004559	1.8	3.0	5603.7	3290.4
2	0.045849	0.077910	0.003338	0.005672	2.2	3.7	4494.0	2644.6
3	0.020695	0.035550	0.001507	0.002588	1.0	1.7	9956.3	5795.9
4	0.052322	0.091250	0.003809	0.006643	2.5	4.3	3938.0	2258.0
5	0.057749	0.102570	0.004204	0.007467	2.8	4.7	3567.9	2008.8
6	0.030683	0.053290	0.002234	0.003880	1.5	2.5	6715.3	3866.5
7	0.021449	0.037390	0.001561	0.002722	1.0	1.8	9606.3	5510.7
10	0.010321	0.018080	0.000751	0.001316	0.5	0.8	19964.2	11396.2